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FMUP FACULDADE DE MEDICINA UNIVERSIDADE DO PORTO

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Sara Fátima Nunes Gomes

# The efficacy of combined adjuvant radiotherapy with surgical excision in the treatment of keloids

# A eficácia da radioterapia adjuvante associada à excisão cirúrgica no tratamento de queloides

**Março, 2020**

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**Mestrado Integrado em Medicina**

**Área: Cirurgia Plástica**
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**Trabalho efetuado sob a Orientação de:**
**Professor Doutor Ricardo José Moreira Horta Oliveira**
**E Coorientação de:**
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The efficacy of combined adjuvant radiotherapy with surgical excision in treatment of keloids

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# Dedicatória

Dedico esta dissertação à minha família.

# Trabalho

# The efficacy of combined adjuvant radiotherapy with surgical excision in the treatment of keloids

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**Keywords:** Keloid, Adjuvant radiotherapy, Surgery, Efficacy

# Abstract

**Purpose:** Keloid scar is a benign dermal condition that occurs due to excessive activation of fibroblast, which leads to an abnormal accumulation of collagen. As a result of its high recurrence rate it is performed nowadays combined treatments. This study aims to evaluate, in real-life patients, the efficacy of adjuvant radiotherapy when used associated with surgical excision.

**Methods:** We conducted a retrospective study on patients with keloid scars who underwent surgical excision and adjuvant radiotherapy, between May 2016 and March 2020. The data was collected from the radiology and plastic surgery medical charts. The patient and observer scar assessment scale (POSAS) was performed in all 13 patients.
The treatment used was surgical removal of the scar associated with 9 Gy radiotherapy dose within the first 24 hours after the surgery, plus another session after 7 days.

**Results:** 13 patients and 16 keloid scars were evaluated during a mean follow-up period of 13,5 months 95%CI (5,84; 21,16). There was no major adverse event from the treatment used. According to POSAS, the overall satisfaction rate was significantly good (mean of 2,29 on a scale from 1 to 10). Only one recurrence was observed (6,25%).

**Conclusion:** Keloid scars are difficult to treat due to their high recurrence rate. There is no consent about which treatment is the best. This study showed that surgical excision combined with adjuvant radiotherapy is an excellent option, even for refractory keloids. The aesthetical result was satisfactory, and the recurrence rate was low.

# Introduction

Keloid is, as well as a hypertrophic scar, a fibroproliferative disorder characterized by an abnormal growth of the tissue scar, due to excessive deposition of collagen(1-3). However, unlike the hypertrophic scars, keloids grow beyond the boundaries of the initial wound.

This scar disorder seems to have the propensity to affect individuals with higher Fitzpatrick phototype, with an incidence ranging from 4,5% to 16% in type VI Fitzpatrick skin type compared to 0,09% in type I (4). It is also known that some genetic conditions increase the probability of having keloids (ex: Noonan syndrome, Bethlem myopathy)(3), as well as a positive family history. The majority of the studies consider that the incidence of keloid scar does affect women and men equally, however Noishiki C, et al concluded that before the age of the normal onset, 15 years old, females have twice the incidence of men(5).

Histologically, keloids are defined by the presence of disarray fibrous nodules and hyalinized thick collagen, which make their appearance unique in size, pigmentation, and pattern(6).

These scars can be asymptomatic or associated with discomfort, pruritus, and pain, which may have a negative impact on the quality of life of patients.

The pathophysiology of this disorder is not well known. However, some studies have found out that the presence of systemic factors, such as hormonal alterations, seen in puberty and pregnancy, can aggravate the inflammation of the tissue, due to the vasodilatory effect that the estrogens have on the vases. Moreover, local risk factors, like delayed wound healing, depth and skin tension also contribute to this process(2).

The inflammation has an important role in the physiology of keloid formation(7) since it is responsible for the continuous activation of the fibroblasts and, consequently, making it impossible for them to mature. Therefore, any condition or event that induces the activation of these cells, in a genetically predisposed individual, can lead to the formation of a keloid scar. Some researchers even consider keloid a chronic inflammatory disease with “cancer-like tendencies”(8), since they have a clinically aggressive behavior although they never metastasize.

There are several different treatments for this condition, which include, compression therapy, silicone gel pads, cryotherapy, injection of glucocorticoids, topical administration of antineoplastic drugs (p. e. bleomycin, 5-FU, mitomycin), immunotherapy (tacrolimus, imiquimod, interferons)(9), surgical resection and radiotherapy. Currently, advancements in other fields like genetic, epigenetic and stem cells are being made with promising results.

Treatment with radiotherapy varies a lot depending on the protocol and the modality used. Renz, P et al showed that the protocol associated with a lower recurrence rate of keloids scar was the dose of 20 Gy in 5 fractions(10).

Keloid scar is a benign condition but refractory to most treatments. As a result of its high risk of recurrence, it is used, nowadays, combined treatment.

This study aims to evaluate the effectiveness of combined treatment- surgical excision associated with adjuvant radiotherapy- in real-life patients. Determine if there was an aesthetic and clinical improvement in the individuals and expose any type of possible complications.

# Methods

## Patients

We performed a retrospective study to evaluate the efficacy of radiotherapy after surgical excision in the treatment of keloids. The study was performed at São João, Porto Hospital and encompassed patients from May 2016 until March 2020. A total of 13 patients, 16 keloid scars were included in this study.

Inclusion criteria were all the patients clinically diagnosed with a keloid scar, who underwent radiotherapy after surgical removal of their keloid. There were no exclusion criteria.

## Radiotherapy protocol

The radiotherapy protocol used in this study was 9 Gy dose applied on the scar within 24 hours after the surgery and another dose applied seven days later.

## Outcome evaluation

The data was gathered from radiology and plastic surgery medical charts with authorized consent of the Ethics Commission. POSAS, Patient and observer scar assessment scale, was performed in all patients to evaluate the physical and symptomatic characteristics of the keloids. The POSAS observer scale was performed by the same investigator in all patients.

The patients were enlisted to attend for reviews of their scar to collect the data for POSAS. For those who could not attend the appointment, the questionnaire was performed by telephone.

The lesions were photographed before and after surgery, and after radiotherapy treatment.

Formal consent was obtained from all the patients below.

Due to the differences between the follow-up time among patients, they were clustered into two categories (follow-up period less than one year and more than one year). The non-parametric test Mann-Whitney was used to compare the answers on both groups.

# Results

A total of 13 patients (5 women and 8 men) underwent surgical excision and radiotherapy treatment. The mean age was 29,2 years with a range between 12 to 69 years. Among patients, 2 were African descendants and 11 were Caucasians.
The mean follow-up period was 13,5 months 95%CI (5,84; 21,16).

## Keloids characteristics

We analyzed 16 keloids. Ten (62,5%) were located in the ear, three (18,75%) in the trunk, one (6,25%) in the mandibular right region, one (6,25%) in the breast and one (6,25%) in the cervical region (Fig. 7).

Eight of the 13 patients referred to had symptoms before the treatment (pain 25% and pruritus 75%).

The main cause for the appearance of the scar, with a total of 5 patients, was iatrogenic (otoplasty, thyroidectomy and mammoplasty), followed by intentional trauma such as piercings (Table 1).

Six patients underwent previous treatments (excisional surgery, corticoids injections, laser and cryotherapy) with poor response.

## The patient and observer scar assessment scale (POSAS)

The POSAS consists of two parts: Patient and Observer scale. Both contains 6 items scored numerically from 1 to 10 (1 corresponds to the characteristics of normal skin and 10 to the worst imaginable scar). The seven-item presented in each scale consists of the overall opinion of the scar. It gives a satisfactory rate of the final lesion.

In the less than a year category, the mean satisfactory rate obtained by the patients was 2,57 (1-10) compared to the 3,43 of the observer scales.

The patients with more than a year follow-up had a mean of 2 (1-10) satisfactory rate, similar to the 2,33 obtained by the observer scale (Table 2).

## Outcome

All of the adverse events caused by the radiotherapy were transient and spontaneous disappeared.

The main event that occurred was erythema (Fig. 5), seen in almost all of the patients. Hyperpigmentation (Fig.4), dry desquamation and focal alopecia were observed in some but, as well as erythema, resolved in weeks.

None of the items of POSAS showed statistically significant differences between groups.

Overall the final lesions had decreased in size, become similar to the natural color of the skin, decreased their symptoms and had a positive impact on the quality of life of patients on both groups.

Only one recurrence was observed among the 16 keloids treated, which makes a recurrence rate of 6,25%.

# Discussion

Keloid scar occurs due to deposition of excessive extracellular matrix on the skin. The major component deposited is collagen that is produced by fibroblasts.
A simple injury can lead to persistent activation of these cells by multiples cytokines and growth factors, such as TGF-ß, PDGF, VEGF, among others(11). Without treatment, these activation cycle of cytokines and collagen progresses over time, increasing the keloid in size and making it more prone to symptoms. The definitive treatment for this skin disorder implies removing this fibrotic tissue and stopping this vicious cycle, preventing it from growing again.

The gold-standard treatment for keloid scars remains unknown. There has been demonstrated over time that some have better results and lower recurrence rates than others. Surgical excision not combined with other treatments does not provide a good response in more than 45% of the patients.(12)

Rabello et al refer that intralesional corticosteroid injections are the first-line therapy. However, it has a recurrence rate of 9% to 50% and a response that significantly range among patients. (13)

Intralesional injections of 5-FU are safe and effective in the treatment of hypertrophic, fibrous and painful scars. The same results were not seen in keloids scars.(14)

Several studies have assessed whether some therapies, such as injection of stem cells, could provide a new optimal outcome for keloid treatment. It has been shown that these cells reduce the keloid implant in the mouse but it is needed more studies to verify the same response in humans. (9)

New therapies with chemotherapy, immunotherapy and anti-hypertension agents have been tested but with no excellent response. (9, 15)

Radiotherapy can be an excellent option to used combined with surgical excision in the treatment of this disorder. This therapy acts by ionizing molecules in irradiated tissues to cause DNA damage, preventing cells to complete their cycle. In keloids, radiotherapy induces the apoptosis and necrosis of fibroblasts, blocking the continuous cycling of cell activation and deposition of collagen. Therefore, it decreases the probability of recurrence regardless the size and location of the keloid.

This study revealed a significantly good overall satisfaction rate with the treatment used.

The group with a follow-up period longer than one year had better results, as should be expected since their lesions had more time to heal and improve aesthetically.

Two of the patients did not achieve good results. One had their keloid returned after 6 months and the other had worsened his lesion, more specifically, it increased in size (Fig.3). Both of the patients were noncompliant with the therapeutics after their radiotherapy sessions, which could explain their final result.

The adverse events observed in patients appeared days after radiotherapy and are completely known as normal early complications of this treatment (erythema and dry desquamation). Hyperpigmentation and focal alopecia were seen in a few patients. All of these complications resolved spontaneously in weeks (Fig.5 e 6).

There were no statistically significant differences between the score given by the two groups to each POSAS item. This can denote that the early lesions caused by radiotherapy on the skin are not significant or do not have such evident impact aesthetically.

Radiotherapy can be aggressive and cause major long-term complications. It can increase the risk of developing tumors in the irradiated region. However, the occurrence of those complications is dose-dependent. The dose used in the benign condition, as keloid scars, is a low to intermediate dose (3-50Gy) which has rare or minimal side effects.(16)

Renz P. et al concluded that lesions treated to >20 Gy had a recurrence rate of 1.6% compared with 9.6% with <20 Gy. (10) Although, the radiotherapy protocol used in this study was 18Gy in 2 fractions for all keloids regardless of their location, the results were still optimal.

The main limitations of this study are the low number of patients and the differences between the follow-up periods among them.

Nevertheless, it still provides strong evidence of the overall improvement of keloid scars of this specific treatment.

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# Tables and figures

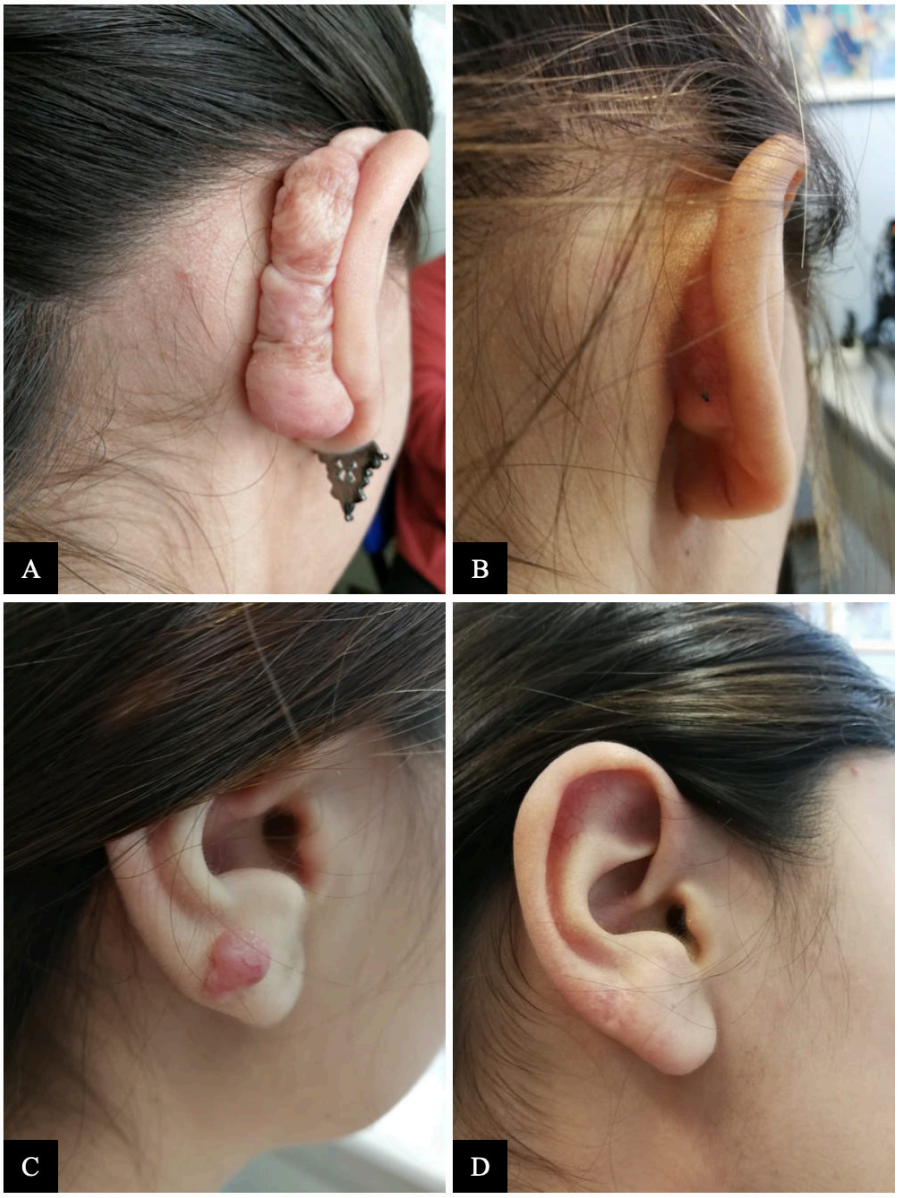



**Fig. 1 A**: Preauricular keloid before treatment. **B**: 24 months of follow-up. **C**: Right earlobe keloid before treatment. **D:** 13 months of follow-up

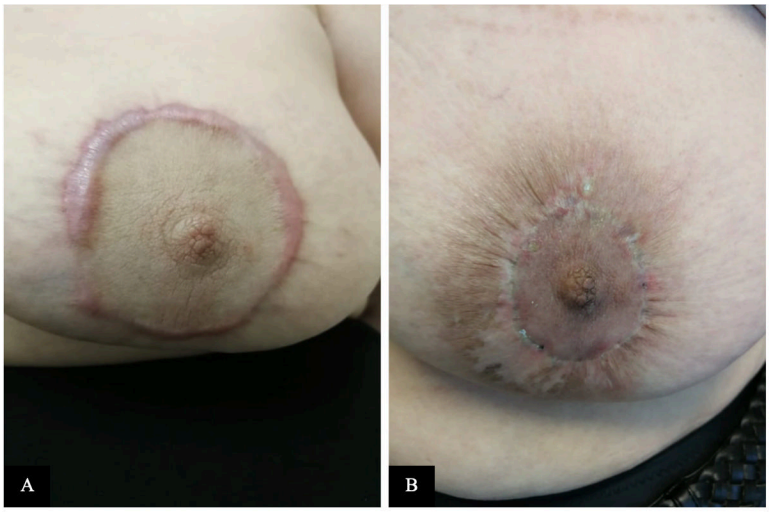



**Fig. 2** **A**: Areolar keloid before treatment. **B**: 1 month of follow-up

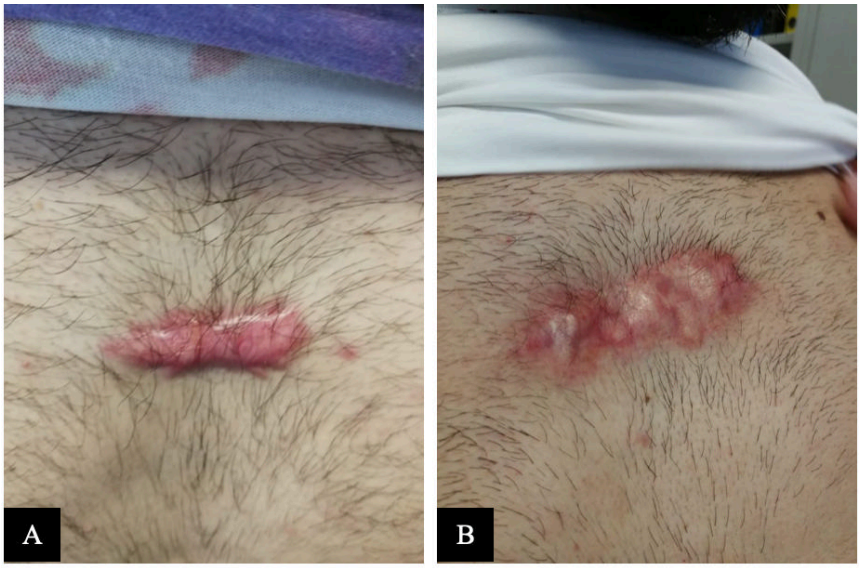



**Fig. 3** **A**: Presternal keloid before treatment. **B**: 5 months of follow-up.

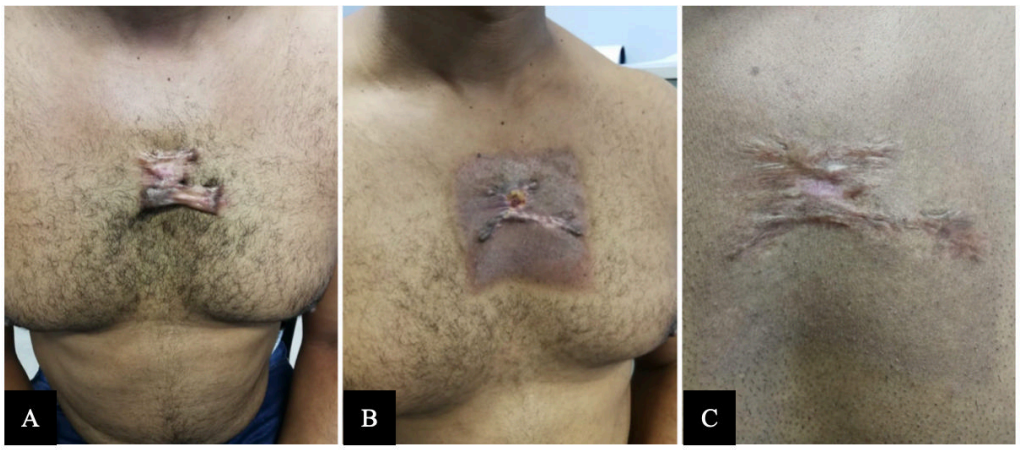



**Fig. 4** **A**: Presternal keloid before treatment. **B**: 1 week after treatment. **C**: 5 months of follow-up

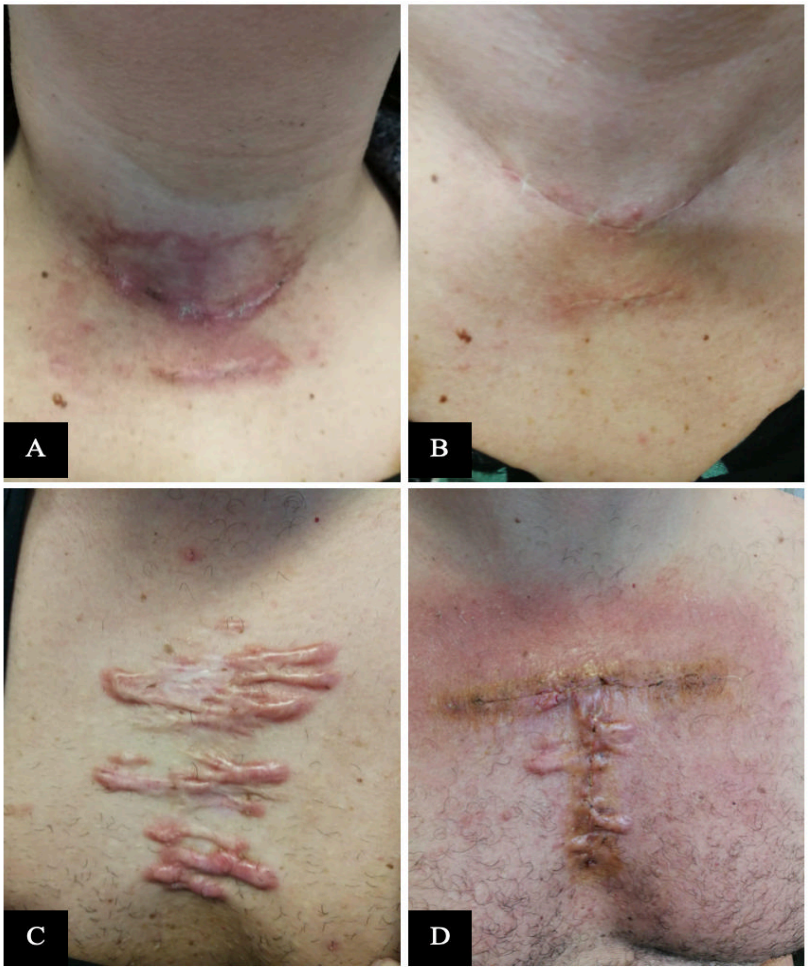



**Fig. 5** Adverse events of radiotherapy **A**: Erythema **B**: 4 weeks of follow-up. **C**: Presternal keloid before treatment. **D**: 2 weeks after partially surgical removal and radiotherapy

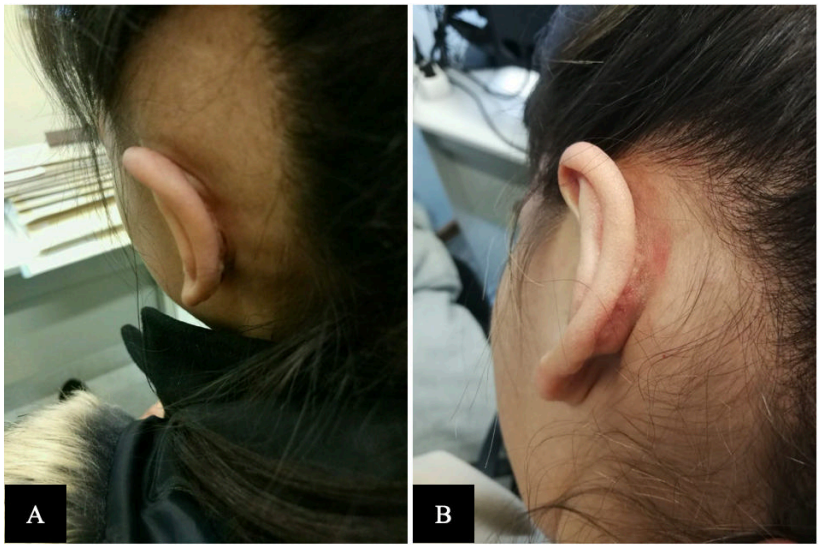



**Fig. 6** Adverse events of radiotherapy. **A**: Focal alopecia. **B**: 24 months of follow-up

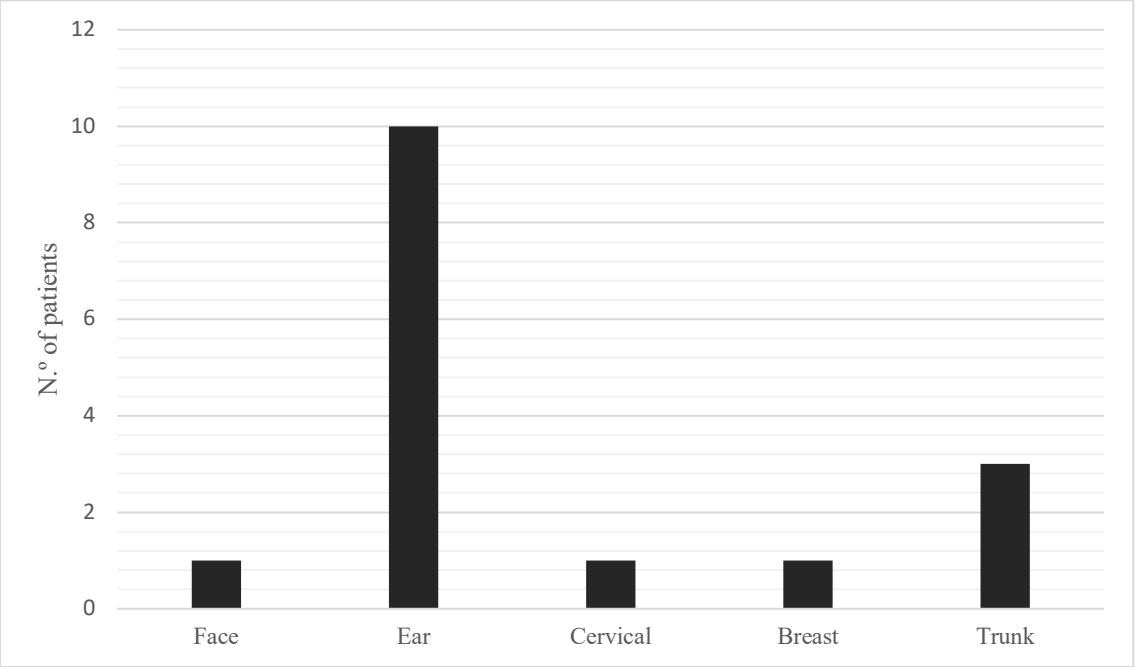



**Fig. 7:** Locations of keloids

**Table 1:** Characteristics of the patients

| **Age** | n=13 |
|---|---|
| min | 12 |
| max | 69 |
| mean | 29,2 |
| **Race** | |
| Caucasian | 11 |
| African | 2 |
| **Cause of Keloid** | |
| Trauma | 3 |
| Intentional | 4 |
| Iatrogenic | 5 |
| Unknown | 1 |
| **Previous Treatments** | |
| Silicone | 1 |
| Corticosteroids | 5 |
| Laser | 1 |
| Liquid Nitrogen | 1 |
| Surgery | 3 |

**Table 2:** Patient and Observer scar assessment scale mean values

| Scale: No, not at all- 1 | | 10- Yes, very much | |
|---|---|---|---|
| | Mean, 95% CI [lower-upper limit] | | |
| | <1 year | >1 year | p value |
| Pain | 1,71 [0,69; 2,74] | 2,67 [0,30; 5,03] | 0,532 |
| Itching | 1,71 [1,02; 2,41] | 1,16 [0,74; 1,60] | 0,135 |
| Scale: No, as normal skin | | Yes, very different-10 | |
| Color | 3,86 [1,11; 6,60] | 1,67 [0,81; 2,52] | 0,065 |
| Stiffness | 4 [0,89; 7,11] | 2,5 [0,54; 4,46] | 0,422 |
| Thickness | 3,86 [0,63; 7,08] | 3 [0,90; 5,10] | 1 |
| Irregularity | 3,57 [0,71; 6,72] | 2,83 [0,69; 4,98] | 0,706 |
| Overall opinion | 2,57 [1,39; 3,75] | 2 [1,34; 2,66] | 0,372 |

Observer Evaluation

| Scale: Normal skin- 1 | | 10-Worst scar imaginable | |
|---|---|---|---|
| | Mean, 95% CI [lower-upper limit] | | |
| | <1year | >1year | p value |
| Vascularization | 3,14 [0,15; 6,14] | 1,67 [0,81; 2,52] | 0,449 |
| Pigmentation | 2,14 [-,27; 4,56] | 1,33 [0,48; 2,19] | 0,629 |
| Thickness | 3,71 [0,18; 7,24] | 2,83 [0,31; 5,35] | 0,816 |
| Relief | 3,43 [0,16; 6,67] | 2,67 [0,21; 5,12] | 0,876 |
| Pliability | 3,43 [0,06; 6,80] | 2,67 [-,20; 5,53] | 0,938 |
| Surface Area | 3,43 [0,06; 6,80] | 2,17 [0,62; 3,71] | 0,876 |
| Overall opinion | 3,43 [0,46; 6,39] | 2,33 [1,25; 3,42] | 0,824 |

# Anexos

# POSAS Patient scale

The Patient and Observer Scar Assessment Scale v 2.0 / EN

**Date of examination:**

**Name of patient:**

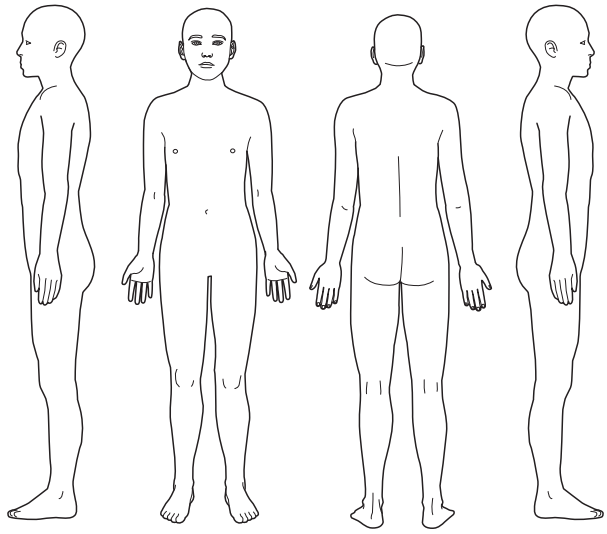
**Observer:**

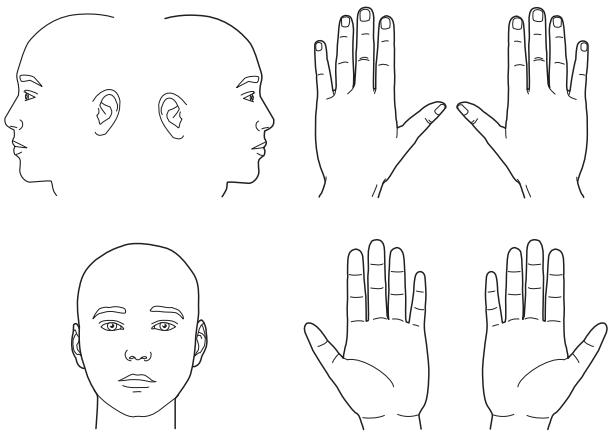
**Location:**

**Date of birth:**

**Research / study:**

**Identification number:**





| | 1 = no, not at all | | | | | | | | | yes, very much = 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| HAS THE SCAR BEEN PAINFUL THE PAST FEW WEEKS? | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| HAS THE SCAR BEEN ITCHING THE PAST FEW WEEKS? | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

| | 1 = no, as normal skin | | | | | | | | | yes, very different = 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| IS THE SCAR COLOR DIFFERENT FROM THE COLOR OF YOUR NORMAL SKIN AT PRESENT? | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| IS THE STIFFNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT? | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| IS THE THICKNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT? | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| IS THE SCAR MORE IRREGULAR THAN YOUR NORMAL SKIN AT PRESENT? | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

| | 1 = as normal skin | | | | | | | | | very different = 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| WHAT IS YOUR OVERALL OPINION OF THE SCAR COMPARED TO NORMAL SKIN? | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

# POSAS Observer scale

The Patient and Observer Scar Assessment Scale v 2.0 / EN

**Date of examination:**

**Name of patient:**

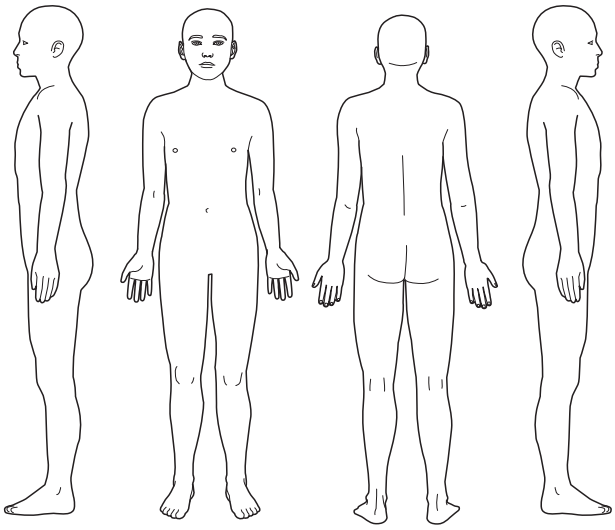
**Observer:**

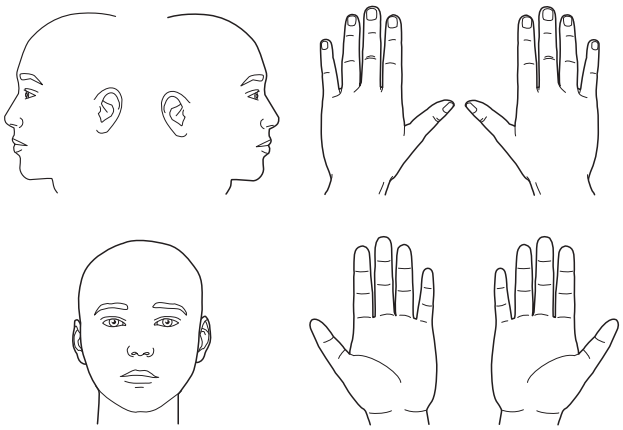
**Location:**

**Date of birth:**

**Research / study:**

**Identification number:**





**1 = normal skin** **worst scar imaginable = 10**

| PARAMETER | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | CATEGORY |
|---|---|---|---|---|---|---|---|---|---|---|---|
| VASCULARITY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | PALE \| PINK \| RED \| PURPLE \| MIX |
| PIGMENTATION | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | HYPO \| HYPER \| MIX |
| THICKNESS | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | THICKER \| THINNER |
| RELIEF | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | MORE \| LESS \| MIX |
| PLIABILITY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | SUPPLE \| STIFF \| MIX |
| SURFACE AREA | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | EXPANSION \| CONTRACTION \| MIX |
| OVERALL OPINION | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | |

## Explanation

The observer scale of the POSAS consists of six items (vascularity, pigmentation, thickness, relief, pliability and surface area).
All items are scored on a scale ranging from 1 ('like normal skin') to 10 ('worst scar imaginable').
The sum of the six items results in a total score of the POSAS observer scale. Categories boxes are added for each item. Furthermore, an overall opinion is scored on a scale ranging from 1 to 10.
All parameters should preferably be compared to normal skin on a comparable anatomic location.

## Explanatory notes on the items:

- **VASCULARITY** Presence of vessels in scar tissue assessed by the amount of redness, tested by the amount of blood return after blanching with a piece of Plexiglas
- **PIGMENTATION** Brownish coloration of the scar by pigment (melanin); apply Plexiglas to the skin with moderate pressure to eliminate the effect of vascularity
- **THICKNESS** Average distance between the subcutical-dermal border and the epidermal surface of the scar
- **RELIEF** The extent to which surface irregularities are present (preferably compared with adjacent normal skin)
- **PLIABILITY** Suppleness of the scar tested by wrinkling the scar between the thumb and index finger
- **SURFACE AREA** Surface area of the scar in relation to the original wound area

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Parecer da Comissão de Ética para a Saúde do
Centro Hospitalar Universitário de São João / Faculdade de Medicina da Universidade do Porto

**Título do Projecto**: A eficácia da radioterapia adjuvante associada à excisão cirúrgica do tratamento de queloides

**Nome da Investigadora Principal:** Sara Fátima Nunes Gomes, estudante do MIM da FMUP

**Onde decorre o Estudo**: No Serviço de Cirurgia Plástica e Reconstrutiva e no Serviço de Radioterapia do CHUSJ. Dispõe de autorização do Dr. Álvaro Silva e da Dra. Gabriela Pinto.

**Objectivos do Estudo:**
Observar o resultado radioterapêutico nos queloides após a sua excisão cirúrgica. Determinar se este tratamento teve bons resultados quer ao nível estético quer por diminuição da sua sintomatologia.

**Concepção e Pertinência do estudo:**
Consulta de registos clínicos de Cirurgia Plástica e Reconstrutiva e de Radiologia, dos doentes do CHUSJ que realizaram este tratamento desde 2015, num total de 15 doentes.
Dados a recolher: idade; raça (considerado pertinente); acontecimento que levou à formação do queloide; localização; tratamentos prévios; data da cirurgia; data das sessões de radioterapia; descrição da cicatriz pelo radiologista antes e após as sessões.
Está previsto também realizar o questionário POSAS (The Patient and Observer Scar Assessment Scale), que prevê uma primeira parte preenchida pelo paciente e a segunda pelo observador (médico assistente ou investigador). Esta última componente consiste numa parte mais descritiva da cicatriz, necessitando por isso a participação presencial do paciente ou o envio de uma foto da cicatriz pelo mesmo. Está prevista a realização do questionário por telefone, caso haja dificuldade para se deslocar ao CHUSJ. A informação será dispensada oralmente ao participante.
Estudo realizado no âmbito do Mestrado Integrado em Medicina da FMUP, sob orientação do Prof. Doutor Ricardo José Moreira Horta Oliveira.

**Benefício/risco:**
A deslocação ao CHUSJ só acontecerá nos casos em que houver consulta de seguimento de radioterapia, ou nos casos em que haja esta disponibilização por parte do participante. Caso contrário, será realizada por via telefónica.

**Confidencialidade dos dados:**
Não serão colhidos dados que possam identificar os doentes. As imagens serão usadas para a descrição do conteúdo do artigo a ser redigido, e serão destruídas após a sua conclusão.
Apresentou um pedido de reutilização de registos clínicos para Investigação e Desenvolvimento ao RAI.

**Respeito pela liberdade e autonomia do sujeito de ensaio**: Não aplicável

***Curriculum* da investigadora**: Adequado à investigação.

**Data previsível da conclusão do estudo**: Março de 2020.

**Conclusão:** Proponho um parecer favorável à realização deste projecto de investigação, na sua actual conformidade.

Porto, 6 de Janeiro de 2020

O Relator da CES,

**Unidade de Investigação**

Tomei conhecimento. Nada a opor. À DC.

03 de Fevereiro de 2020

A Coordenadora da Unidade de Investigação

(Prof.ª Doutora Ana Azevedo)

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## *Nome do Investigador Principal:*

Sara Fátima Nunes Gomes

## *Título da Investigação:*

A eficácia da radioterapia adjuvante associada à excisão cirúrgica do tratamento de queloides

*Pretendendo realizar no(s) Serviço(s) de:*

Cirurgia Plástica e Reconstrutiva e Radioterapia

*a investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, autorização para a sua efetivação.*

*Para o efeito, anexo toda a documentação referida no dossier da Comissão de Ética do Centro Hospitalar de São João/ Faculdade de Medicina da Universidade do Porto respeitante à investigação, à qual enderecei pedido de apreciação e parecer.*

*Com os melhores cumprimentos.*

*O Investigador/ Promotor*

*Porto,* 09 *de* Dezembro *de* 2019 . Sara Fátima Nunes Gomes

*assinatura*

• Centro Hospitalar São João •
Centro de Epidemiologia Hospitalar
14/1/2020

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# Questionário para submissão de Investigação

*Exmo. Sr. Presidente da Comissão de Ética do Centro Hospitalar de São João/ Faculdade de Medicina da Universidade do Porto,*

*Pretendendo realizar a investigação infracitada, solicito a V. Exa., na qualidade de Investigador, a sua apreciação e a elaboração do respetivo parecer. Para o efeito, anexo toda a documentação requerida.*

## IDENTIFICAÇÃO DO ESTUDO

**Título da investigação:** A eficácia da radioterapia adjuvante associada à excisão cirúrgica no tratamento de queloides

**Nome do investigador:** Sara Fátima Nunes Gomes

**Endereço eletrónico:** sara.n.gomes1994@hotmail.com **Contacto telefónico:** 962971662

**Caracterização da investigação:**

☒ Estudo retrospetivo ☐ Estudo observacional ☐ Estudo prospetivo

☐ Inquérito ☐ Outro. Qual? _____

**Tipo de investigação:**

☐ Com intervenção ☒ Sem intervenção

**Formação do investigador em boas práticas clínicas *(GCP)*:** ☐ Sim ☐ Não

**Promotor** *(se aplicável)*: _____

**Nome do orientador de dissertação/tese** *(se aplicável)*: Ricardo José Moreira Horta Oliveira

**Endereço eletrónico:** ricardojmhorta@gmail.com

**Local/locais onde se realiza a investigação:** Hospital São João

Data prevista para início: 20 / 10 / 19 Data prevista para o término: 30 / 11 / 19

## PROTOCOLO DO ESTUDO

**Síntese dos objetivos:**

Observar o resultado radioterapêutico nos queloides após a sua excisão cirúrgica. Determinar se este tratamento teve bons resultados quer ao nível estético quer por diminuição da sua sintomatologia.

**Fundamentação ética (ganhos em conhecimento/inovação; ponderação benefícios/riscos):**

Relativamente aos potenciais riscos creio que não haverão neste estudo, uma vez que, este é um estudo retrospectivo no qual não existe nenhuma intervenção. Os dados necessários para este artigo serão pedidos aos pacientes através de um questinário (POSAS) e fotos do queloíde antes e após o tratamento.

Este artigo visa determinar a eficácia ou não deste tipo de tratamento nestes doentes, observar a sua evolução ao longo do processo e verificar se, para estes, os benefícios ultrapassaram os riscos.

## CONFIDENCIALIDADE

**De que forma é garantida a anonimização dos dados recolhidos de toda a informação?**

O nome dos pacientes não serão usados para a construção do artigo. As imagens utilizadas serão usadas apenas para descrição teórica do seu conteúdo. As imagens que eventualmente forem colocadas no artigo apenas o serão com o

**O investigador necessita ter acesso a dados do processo clínico?** ☒ Sim ☐ Não

**Está previsto o registo de imagem ou som dos participantes?** ☒ Sim ☐ Não

**Se sim, está prevista a destruição deste registo após o sua utilização?** ☒ Sim ☐ Não

## CONSENTI MENTO

**O estudo implica recrutamento de:**

Doentes: ☐ Sim ☒ Não Voluntários saudáveis: ☐ Sim ☐ Não

Menores de 18 anos: ☒ Sim ☐ Não

Outras pessoas sem capacidade do exercício de autonomia: ☐ Sim ☒ Não

**A investigação prevê a obtenção de Consentimento Informado:** ☒ Sim ☐ Não

**Se não, referir qual o fundamento para a isenção:**

**Existe informação escrita aos participantes:** ☒ Sim ☐ Não

## PROPRIEDADE DOS DADOS

**A investigação e os seus resultados são propriedade intelectual de:**

☐ Investigador ☐ Promotor ☒ Ambos ☐ Serviço onde é realizado

☐ Não aplicável Outro: _____

## BENEFÍCIOS, RISCOS E CONTRAPARTIDAS PARA OS PARTICIPANTES

**Benefícios previsíveis:**

**Riscos/incómodos previsíveis:**

**São dadas contrapartidas aos participantes:**

- ***pela participação*** ☐ Sim ☒ Não ☐ Não aplicável
- ***pelas deslocações*** ☐ Sim ☐ Não ☒ Não aplicável
- ***pelas faltas ao emprego*** ☐ Sim ☐ Não ☒ Não aplicável
- ***por outras perdas e danos*** ☐ Sim ☐ Não ☒ Não aplicável

## CUSTOS / PLANO FINANCEIRO

**Os custos da investigação são suportados por:**

☐ Investigador ☐ Promotor ☐ Serviço onde é realizado

☒ Não aplicável Outro: _____

**Existe protocolo financeiro?** ☐ Sim ☒ Não

## LISTA DE DOCUMENTOS ANEXOS

- [x] Pedido de autorização ao Presidente do Conselho de Administração do Centro Hospitalar de São João *(se aplicável)*
- [ ] Pedido de autorização à Diretora da Faculdade de Medicina da Universidade do Porto *(se aplicável)*
- [x] Protocolo do estudo
- [x] Declaração do Diretor de Serviço onde decorre o estudo
  *(sendo um estudo na área de enfermagem deve anexar também a concordância da chefia de enfermagem)*
- [x] Profissional de ligação
- [ ] Informação dos orientadores
- [x] Informação ao participante
- [x] Modelo de consentimento
- [x] Instrumentos a utilizar *(inquéritos, questionários,escalas, p.ex.)*: Questionário POSAS
- [x] Curriculum Vitae abreviado *(máx. 3 páginas)*
- [ ] Protocolo financeiro
- [ ] Outros:

## COMPROMISSO DE HONRA E DECLARAÇÃO DE INTERESSES

*Declaro por minha honra que as informações prestadas neste questionário são verdadeiras. Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes da Declaração de Helsínquia (1960 e respetivas emendas), e da Organização Mundial da Saúde, Convenção de Oviedo e das "Boas Práticas Clínicas" (GCP/ICH) no que se refere à experimentação que envolve seres humanos. Aceito, também, a recomendação da CES de que o recrutamento para este estudo se fará junto de doentes que não tenham participado em outro estudo, nos últimos três meses. Comprometo-me a entregar à CES o relatório final da investigação, assim que concluído.*

*Porto,* 20 *de* Outubro *de* 2019

*Nome legível:* Sara Fátima Nunes Gomes

Sara Fátima Nunes Gomes
*assinatura*

***Parecer da Comissão de Ética do Centro Hospitalar de São João/ FMUP*** Emitido na reunião plenária da CE de 19 / 12 / 19

Aguardo esclarecimentos.

Prof. Doutor Filipe [illegible]
Presidente da Comissão de Ética

Centro Hospitalar **São João**.

CONSIDERADOS QUE FORAM COMO SATISFATÓRIOS OS ESCLARECIMENTOS PRESTADOS PELO(A) INVESTIGADOR(A), A CES APROVA POR UNANIMIDADE O PARECER DO RELATOR PELO QUE NADA TEM A OPOR À REALIZAÇÃO DESTE PROJETO DE INVESTIGAÇÃO.

06/01/2020

Prof. Doutor [illegible]
Presidente da Comissão de Ética

RESPONSÁVEL PELO ACESSO À INFORMAÇÃO

SÃO JOÃO

# Pedido de Reutilização de Registos Clínicos para Investigação e Desenvolvimento (I&D)

Número do Pedido: 2020022815
*(A preencher pelo Gabinete de Apoio ao RAI)*

*Exmo. Senhor*
*Responsável pelo Acesso à Informação*
*(Artigo 9.º da Lei n.º 26/2016, de 22 de agosto)*
*Dr. Rui de Vasconcellos Guimarães*

SÃO JOÃO

AUTORIZADO
RAI - Responsável pelo Acesso à Informação do Centro Hospitalar de São João
(Art.º 9º, Lei 26/2016, de 22/8)
10/01/20

## 1. Identificação do(s) Investigador(es) *Preenchimento Obrigatório*

### 1.1. Investigador Principal

Nome: Sara Fátima Nunes Gomes
Contacto telefónico: 962971662
Endereço eletrónico: sara.n.gomes1994@hotmail.com

### 1.2. Investigador(es) Associado(s)

**Número Total:** ☐

Nome: _____
Contacto telefónico: _____
Endereço eletrónico: _____ @ _____

Nome: _____
Contacto telefónico: _____
Endereço eletrónico: _____ @ _____

Nome: _____
Contacto telefónico: _____
Endereço eletrónico: _____ @ _____

### 1.3. Afiliação Institucional do Investigador Principal

#### 1.3.1. Grupo Profissional

☐ Médico(a) ☐ Enfermeiro(a) ☐ Docente ☒ Estudante
☐ Outro. Qual? _____

#### 1.3.2. Documento de identificação pessoal ou profissional

☐ Cartão de Cidadão ☐ Bilhete de Identidade ☐ Célula Profissional
☐ Cartão de Docente ☒ Cartão de Estudante ☐ Outro. Qual? _____

Número de Documento: 13856556

## 2. Enquadramento e Identificação do Trabalho de Investigação e Desenvolvimento *Preenchimento Obrigatório*

### 2.1. Enquadramento da investigação

☒ Trabalho académico de investigação e desenvolvimento:
- ☐ Não conferidor de grau
- ☐ Conferidor de grau: ☐ Licenciatura ☒ Mestrado ☐ Doutoramento

☐ Projeto de investigação e desenvolvimento

RAI-IM002-0

**2.2. Entidade(s) que tutela(m) a investigação**

☒ *Centro Hospitalar de São João*
*Serviço:* Cirurgia Plástica e Reconstrutiva

☒ Universidade do Porto
*Faculdade / Instituto:* Faculdade de Medicina

☐ Outra Instituição. *Qual?* _____

**Há alguma parceria entre instituições?**

☐ Não ☐ Sim. Qual(is)? _____

**2.3. Orientador** *Se Aplicável*

Contacto telefónico 917146306

Endereço eletrónico ricardojmhorta@gmail.com

**2.4. Título provisório**

A eficácia da radioterapia ajuvante associada à excisão cirúrgica no tratamento de queloides.

The efficacy of combined adjuvant radiotherapy with surgical excision in the treatment of keloids

*Deverá posteriormente indicar o título definitivo para emissão do Certificado de Reutilização pelo RAI – DAta REuse Certificate for Research – DARE através dos contactos disponíveis no fim deste formulário.*

**2.5. Acesso requerido**

☐ Ficheiro

*Descrição do património informacional a que pretende ter acesso, identificando a informação a obter, i.e. nome, morada, diagnóstico, idade, códigos dos distritos, entre outros.*

☐ Consulta de processos clínicos em ambiente papel:

☐ Bloco ☒ Consulta Externa ☐ Hospital de Dia ☒ Internamento ☐ MCDT ☐ Urgência

*Deverá anexar ficheiro(s) contendo a identificação do pretendido, i.e. números de processos, episódios, números de utente, entre outros.*

Anexar ficheiro no ato de envio

☐ Consulta de registos clínicos eletrónicos

*Especificar os Sistemas de Informação:*

SClínico.

Data previsível de fim de utilização das credenciais de acesso 2019-12-30

☐ Outro Acesso. Qual?

**2.3. Pareceres e Autorizações**

☐ Autorização da Hierarquia
☐ Protocolo Científico Aprovado [1]
☒ Parecer da Comissão de Ética para a Saúde (CES) [1]
☐ Parecer do Centro de Epidemiologia Hospitalar [1]

*Deverá anexar ficheiro(s) contendo cópia dos documentos referentes às opções selecionadas.*

Anexar ficheiro no ato de envio

[1] *Obrigatório quando aplicável.*

## 3. Observações *Preenchimento Facultativo*

## 4. Aceitação dos Termos e Condições da Reutilização

Cumulativamente com as obrigações decorrentes da lei já citada *(n.º 2 e 3 do artigo 21 e o n.º 1 e 2 do artigo 12, ambos da Lei n.º 26/2016, de 22 de agosto)* ao submeter o presente pedido concordo e fico ainda vinculado aos seguintes termos e condições:

- Comprometo-me a manter confidencial toda a informação à qual vou ter acesso;
- Não vou elaborar registos, susceptíveis de identificar ou tornar identificável a identidade das pessoas a quem os mesmos dizem respeito;
- Não vou elaborar, nem ficar na posse, de cópias de bases de dados utilizadas na recolha de informação;
- Comprometo-me a obter junto da Comissão Nacional de Proteção de Dados (CNPD) as necessárias autorizações, para eventuais bases de dados que venha a conceber e utilizar no âmbito da presente investigação;
- Comprometo-me a devolver ao Centro Hospitalar de São João, na pessoa do seu Diretor Clínico, as bases de dados e o resultado da investigação;
- Comprometo-me a ocultar os elementos de identificação da(s) pessoa(s) a quem os registos digam respeito, em futuras e eventuais publicações de resultados;
- Comprometo-me a consultar os processos clínicos nas instalações que me forem indicadas para o efeito;
- Comprometo-me a obter os necessários pareceres, quer da Comissão de Ética do Hospital, quer do Centro de Epidemiologia Hospitalar, sempre que necessário;
- Comprometo-me a citar as fontes sempre que publicitar o trabalho de investigação independentemente de requerer a Certidão de Reutilização (DAta REuse Certificate for Research – DARE);
- Tomei conhecimento, que a violação de qualquer dos compromissos aqui assumidos, resultará no apuramento de responsabilidades disciplinares, civis e penais e ainda, à impossibilidade futura de aceder a informação de saúde para fins de investigação.

## 5. Decisão do investigador sobre requerer a DAta REuse Certificate for Research – DARE *Preenchimento Obrigatório*

☒ Pretendo desde já requerer a Certidão de Reutilização (DARE) cujo sentido, valor e significado consultei em *http://portal-chsj.min-saude.pt/pages/710.*

☐ Não pretendo requerer a Certidão de Reutilização (DARE) cujo sentido, valor e significado consultei em *http://portal-chsj.min-saude.pt/pages/710.*

## 6. Assinatura

*Nota 1: Se o presente pedido for submetido eletronicamente ou faz assinatura digital qualificada; ou posteriormente vem ao Centro Hospitalar de São João exibir o seu documento de identificação pessoal; ou no âmbito do seu espaço de liberdade e como manifestação expressa do seu consentimento envia cópia do referido documento, neste caso, concluído o processo ser-lhe-á devolvida ou eliminada a cópia do documento de identificação pessoal, conforme as indicações que dê.*
*Nota 2: Se o presente pedido for entregue presencialmente, assina e exibe o documento de identificação a quem recebe o pedido.*

Data 2019 - 10 - 20

Sara Raimundo Nunes Gomes

***Investigador Principal***

**Em caso de dúvida no preenchimento contacte através dos endereços eletrónicos**
rai.reutilizacao.id@chsj.min-saude.pt **ou** ruiguimaraes@chsj.min-saude.pt
**ou pelos números de telemóvel** 962 204 194 **ou** 918 880 299

SUBMETER