

BMJ Open Continuous and interrupted abdominal-wall closure after primary emergency midline laparotomy (CONIAC-trial): study protocol for a randomised controlled single centre trial

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ABSTRACT

Introduction The optimal closure of the abdominal wall after emergency midline laparotomy is still a matter of debate due to lack of evidence. Although closure of the fascia using a continuous, all-layer suture technique with slowly absorbable monofilament material is common, complications like burst abdomen and hernia are frequent.

Methods and analysis This randomised controlled trial with a 1:1 allocation evaluates the efficacy and safety of a continuous suture with or without additional interrupted retention sutures for closure of the abdominal fascia. Patients with an indication for a primary emergency midline laparotomy are eligible to participate in this study and will be randomised intraoperatively via block randomisation. Fascia closure in the intervention group will be done with a standard continuous suture with slowly absorbable monofilament material (MonoMax 1, B. Braun, Tuttlingen, Germany) and additional interrupted retention sutures every 2 cm of the fascia using rapidly absorbable braided material (Vicryl 2, Ethicon, Norderstedt, Germany). In the control group, the fascia is closed only with the standard continuous suture with slowly absorbable monofilament material. Sample size calculations (n=111 per study arm) are based on the available literature. The primary endpoint is the rate of dehiscence of the abdominal fascia (rate of burst abdomen within 30 days or rate of incisional hernia within 12 months). Secondary endpoints are wound infections, quality of life, length of hospital stay, morbidity and mortality. Patients as well as individuals involved in data collection, endpoint assessment, data analysis and quality of life assessment will be blinded.

Ethics and dissemination The study protocol, the patient information and the informed consent form have been approved by the ethics committee of the Ludwig-Maximilians-University, Munich, Germany (reference number: 20-1041). Study findings will be submitted for publication in peer-reviewed journals.

Trial registration number DRKS00024802.

WHO universal trial number U1111-1259-1956

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This trial may lead to further evidence for the optimal closure technique of emergency midline laparotomies.
- ⇒ The prospective, randomised design of the trial with a 1:1 allocation will reduce potential bias.
- ⇒ The inclusion of patients undergoing primary midline laparotomy only for an emergency indication, will lead to a homogeneous study population.
- ⇒ The use of the SF-36-Health-Survey and Wound-Quality of Life questionnaire will increase measurement precision for core quality of life domains.
- ⇒ This trial compares only two specific methods for fascial closure and does not compare other techniques and suturing materials.

INTRODUCTION

In Germany, more than 700 000 laparotomies are performed annually. The most common late complications after laparotomy because of fascia dehiscence are incisional hernias. The incidence of incisional hernias 1 year after surgery is around 9%–20%,^{1 2} but can rise up to over 35% in patients with risk factors.³ This represents a major health and social problem. An incisional hernia is often associated with pain and limitations in professional life. Although agreement in choice of treatment strategy for patients with incisional hernias among surgeons is low, these hernias often require surgical treatment with corresponding perioperative risks.⁴ An early postoperative fascia dehiscence leads to the formation of a burst abdomen. The rate of reoperation due to a burst abdomen is 1%–3% according to the literature.^{2 5} Many studies have been conducted over the last few years to find the best method for abdominal wall closure after laparotomies. Thus, there are a lot of trials comparing a continuous

with a interrupted suturing technique, fast with slowly absorbable suture material and small (ratio of suture to wound length of at least 4/1) with large stitch spacing of the suture method.

The guideline of the European Hernia Society recommends a continuous suture with a slowly absorbable monofilament thread in the ‘small bites’ technique (stitch distance to fascia edge 5–8 mm, distance between stitches 5 mm⁶) with a ratio of suture to wound length of at least 4/1 for the closure of elective midline laparotomies.⁷ There is strong evidence for this technique to prevent incisional hernias—the slowly superior the fast absorbable suture materials and the ‘small bites’ the ‘large bites’ technique.^{8,9}

For the closure of laparotomies in emergency procedures, which are associated with an increased risk of wound dehiscence, burst abdomen and as result also incisional hernia,¹⁰ no recommendation for a special suturing technique can be made due to a lack of evidence.⁷ The frequency of fascia dehiscence correlates with several risk factors, for example, hypoalbuminaemia, anaemia, malnutrition, chronic lung diseases or post-operative vomiting and ileus.^{10,11} In these cases, some studies recommend the use of additional retention sutures to reduce tension on the fascia suture and thus allow a better healing. Such a technique can reduce the rate of burst abdomen and hernias¹² and their use has also been suggested as a treatment choice for managing fascial dehiscence.^{13,14} However, the guideline of the European Hernia Society does not make a recommendation for routine use of this fascia closure technique due to a lack of evidence.⁷ In addition, these sutures are associated with increased pain, postoperative discomfort, skin maceration and wound complications, as they pass through the entire abdominal wall, that is, fascia, subcutaneous fat and skin.¹⁵ Due to this, routine application of this technique has not been well accepted. Nevertheless, that prophylactic retention sutures could be an option in high-risk patients with multiple risk factors for preventing fascia dehiscence without imposing remarkable postoperative complications.¹² The negative side effects could be reduced by performing subcutaneous retention sutures without involving the skin.¹⁶ However, prospective data are lacking.

Rationale for this randomised trial

There is still lack of evidence for the optimal closure technique for emergency midline laparotomies. The continuous suture technique in combination with intermediate sutures could reduce the increased rate of fascial dehiscence in the emergency setting. To avoid the increased pain of penetrating retention sutures, these sutures should only be stitched through the abdominal wall fascia. However, it is not yet clear whether this suture technique is superior to continuous suturing alone in the emergency situation and does not lead to more wound complications. This should be analysed in this randomised trial.

METHODS

Trial design and study population

The CONIAC (continuous and interrupted abdominal-wall closure after primary emergency midline laparotomy) trial is a single-centre, randomised controlled superiority trial featuring a two-arm parallel group design with a 1:1 allocation ratio. The flow chart of the study is shown in [figure 1](#). Patients who require a primary emergency operation via midline laparotomy due to an acute disease of the abdominal visceral organs are screened for inclusion. Participants will be randomised either to the intervention or the control group.

Informed consent

Each patient included in the study must be able to provide written informed consent prior to participation (see online supplemental file 1, patient consent form). Due to the emergency situation, the informed consent takes place shortly before the visceral surgical procedure and will be carried out by the staff surgeons of the University Hospital Augsburg. This procedure was approved by the local ethics committee.

Eligibility criteria

Patients who need to undergo a primary emergency operation via midline laparotomy must be at least 18 years old with a survival expectancy of at least 12 months to be eligible to participate in the study.

Exclusion criteria

Incapacitated patients, underage patients, pregnant patients and patients with immune system impairments, serious psychiatric disorders and lack of compliance are excluded from the study participation. Other exclusion criteria are a lack of understanding (linguistic or cognitive) for study instructions, chemotherapy or radiotherapy up to 2 months before surgery, and an existing midline laparotomy (excluding condition after laparoscopic surgery, cholecystectomy, hysterectomy and section, transverse laparotomy). In addition to these preoperative criteria, the septic source must be successfully controlled and in case of peritonitis abdominal lavage must be performed prior to intraoperative randomisation.

Secondary exclusion criteria and adverse events

Patients who must undergo a relaparotomy within 30 days after the primary operation via midline laparotomy or die within this period will be secondarily excluded from the study. Any adverse event (AE) or unintended effect of the trial interventions will be documented and assessed.

Data assessment and study plan

Patients’ demographic data, intraoperative findings, the cause for operation and the associated surgical treatment will be documented. In addition, the length of skin and fascia incision will be captured.

There will be six visits within the whole trial ([table 1](#)). There will be two visits during the hospital stay, on day 2±1 postoperatively (visit 3) and on the day of discharge

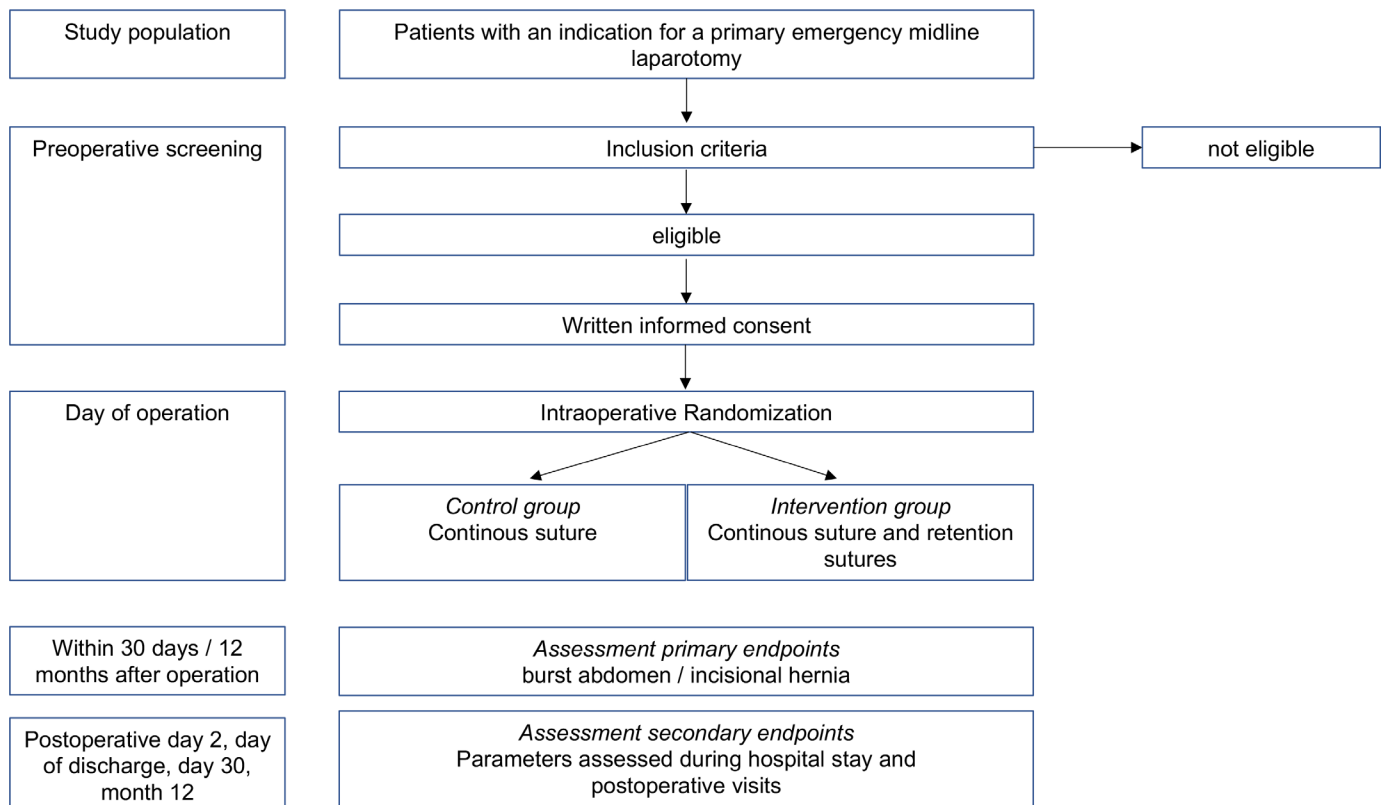


Figure 1 Flow chart of the CONIAC (continuous and interrupted abdominal-wall closure after primary emergency midline laparotomy) trial.

(visit 4). On these visits data on postoperative complications (according to the Clavien-Dindo classification¹⁷), length of hospital stay, pulmonary complications and especially on wound healing disorders, in order to record burst abdomen, is collected.

Follow-up visits are carried out on day 30 after surgery (visit 5) and 12 months after surgery (visit 6). On these visits, besides clinical examination of the abdominal wall, an ultrasound will be performed to assess the primary endpoint. Quality of life is assessed using a validated questionnaire (Short Form (SF)-36 V.1.1 Health Survey¹⁸), which has previously been used in trials on surgical interventions. Furthermore, the Wound-Quality of Life questionnaire¹⁹ will be used to assess how patients' cope with their wounds.

Endpoints

The primary endpoint of the CONIAC trial is the incidence of postoperative fascia dehiscence, defined as a burst abdomen within 30 days or an incisional hernia within 12 months after operation.

A burst abdomen is present if there is a gap in the continuity of the abdominal fascia (assessed either by clinical or radiologic diagnostics) with a wound dehiscence and/or a consecutive relapse operation occurring up to day 30 after surgery.

Incisional hernias will be assessed in the 12 months visit either by examination of an experienced surgeon and ultrasound of the abdominal wall by an experienced

radiologist in the study centre. Therefore, the surgeon must be experienced in abdominal wall examination and must not be involved in the treatment or operation of the patient. An incisional hernia is defined as a protruding sac of the abdominal cavity through the fascia in the ultrasound and must be confirmed by clinical examination.

There will be several surgical and non-surgical parameters assessed as secondary endpoints as shown in [table 2](#).

Surgical procedures and trial intervention

There will be a standardised treatment of the operated patients except to the closure of the abdominal wall, which will be performed according to the study protocol. All patients receive perioperative antibiotic prophylaxis according to local standards or antibiotic therapy depending on clinical situation. The skin and subcutaneous tissue will be cut by electric cautery, the fascia and peritoneum will be opened using scissors. The intra-abdominal surgical interventions will be performed according to the underlying disease in a standardised way independently to study enrolment. If there is a septic focus, intra-abdominal swabs for microbiological diagnostics, abdominal lavage and the placement of intra-abdominal drains will be made. Furthermore, the antibiotic treatment will be continued and adjusted according to the swab results.

Before closing the abdominal wall, eligible patients will be randomised in the two treatment groups. In the intervention group the abdominal fascia will be closed using

Table 1 Studyplan CONIAC (continuous and interrupted abdominal-wall closure after primary emergency midline laparotomy) trial

	Visit 1 (Screening/preoperative)	Visit 2 (day 0)	Visit 3 (day 2±1)	Visit 4 (day of discharge)	Visit 5 (day 30±5)	Visit 6 (month 12±1 postsurgery)
Informed consent	x					
Demographic data	x					
Inclusion/exclusion	x					
Medical history	x					
Reason for surgery	x					
Physical examination	x		x	x	x	x
Surgery		x				
Randomisation		x				
Abdominal AE/SAE		x	x	x	x	x
Ultrasound abdomen					x	x
Burst abdomen			x	x	x	x
Wound infection			x	x	x	x
Incisional hernia			x	x	x	x
Quality of life (SF (Short Form)-36, wound questionnaire)					x	x
Discharge				x		

AE, adverse event; SAE, serious adverse event.

a running suture in combination with interrupted retention sutures. The continuous suture will be performed as a suture of the abdominal fascia with two slowly absorbable, monofilament MonoMax loops (B. Braun, Tuttlingen, Germany). Therefore, a 'small bites' suturing technique in an at least suture to wound length ratio of 4/1 will be used.²⁰ The first stitches of the two loops will be made cranial and caudal of the fascia incision. After closing half of the length of the wound, the needle will be cut of both strings, one of the loop strings threaded in the last loop of the suture and then both ends tied together with at least four counterrotating knots. The same procedure will be performed with the second MonoMax loop beginning at the opposite end of the fascia incision and overlapping the first suture in the middle for at least 2 cm. The distance between the stitches and to the margin of the fascia should not exceed 0.5 cm.

In addition to this suture, interrupted retention sutures must be made. Therefore, a polyfilament, resorbable Vicryl 2 (Ethicon, Norderstedt, Germany) suture is used. The sutures are made every 2 cm beginning at one end of the incision with a distance of 2 cm from the edge of the fascia. To enable correct execution of the stitches, they are performed during the continuous suture. Meanwhile, the continuous thread is kept under tension. Once all stitches are done, each suture is tied with at least four

counter-rotating knots. There is no additional dissection of the fascia for placing the retention sutures.

In the control group, the fascia is closed only with the two MonoMax 1 loops as described above.

The subcutaneous tissue is not sutured and no subcutaneous drainage is used. The skin will be closed with clips and the skin and thus the fascia incision will be measured.

Assessment of safety

Safety of patients will be primarily assessed with annual safety reports (ASR) according to the declaration of Good Clinical Practice § 13, passage 6. As part of the ASR, adverse and serious AE will be recorded. To maintain patient safety, there will be clinical and ultrasound examinations of the abdominal wall 30 days and 12 months after operation. To detect long-range AEs, the secondary endpoints wound infection, wound pain, suture granuloma, mortality, reoperation, quality of life and duration of hospital stay will be assessed.

Randomisation and blinding

Participants will be randomised intraoperatively before closure of the abdominal wall with sealed, opaque envelopes. Block randomisation will be performed with randomisation numbers allocated to the two groups in balanced permuted blocks to ensure equal-sized groups. The size

Table 2 Secondary endpoints of the CONIAC (continuous and interrupted abdominal-wall closure after primary emergency midline laparotomy) trial

Secondary endpoint	Definition
Frequency of wound infection	Surgical site infections 30 days after operation
Frequency of re-operation due to burst abdomen	Surgical intervention indicated due to the occurrence of burst abdomen after intervention
Frequency of reoperation	Any laparotomy at any time during the follow-up period
Quality of life (QoL)	SF (Short Form)-36 and wound-QoL questionnaire filled in by the patient 30 days and 12 months after operation
Length of skin and fascia incision	Length of the abdominal wound from the upper to the lower pole in cm
Chronic wound pain	Assessment by clinical examination 30 days and 12 months after operation
Frequency of thread granuloma	Assessment by clinical examination and ultrasound 30 days and 12 months after operation
Postoperative duration of hospital stay	From the day of the operation until the day of discharge (days)
Postoperative duration of stay on the intensive care unit	Time from admission to the intensive care unit until transfer to the regular ward (days)
Postoperative complications	Graded after Clavien-Dindo ¹⁷
Mortality	Death due to any cause at any time during the follow-up period
Duration of vacuum therapy	From first placement of the sponge to removal of the sponge (days)
Time to first bowel movement	From the day of surgery until day of patient's first bowel movement
Postoperative pulmonary infections	Every pulmonary infection after index operation during the first hospital stay (elevated blood inflammation parameters in combination with an infiltration in the chest X-ray)
Duration of postoperative artificial ventilation and haemodialysis	Time on the respirator and the need for haemodialysis postoperatively (days)

of the individual blocks will only be disclosed after the study has been completed so as not to allow prediction of group allocation. A sufficient number of subjects will be recruited according to the sample size calculation to minimise random errors and to ensure sufficient power to test the hypothesis of the primary endpoint. Randomisation will be performed by individuals not involved in the surgical procedure, data evaluation, data analysis, postoperative care and follow-up of the patients. When the study is finished, all unopened envelopes will be compared with the allocated randomisation numbers and checked for completeness.

Patients as well as individuals involved in data collection, endpoint assessment, data analysis and quality of life assessment will be blinded. Participating surgeons will be instructed which treatment procedures. Blinding of surgeons is not feasible due to the nature of the interventions. To reduce bias, these surgeons are not involved in data collection or analysis. Nurses and doctors assessing the endpoints on the ward are blinded.

Sample size calculation

The sample size calculation is based on the primary endpoint 'postoperative fascia dehiscence'. In this respect, the incidence of burst abdomen and incisional hernia after emergency midline laparotomy is conservatively esteemed around 23% in literature.² Only few studies evaluated the effect of additional retention

sutures. A prospective, randomised trial found lower rates of fascia dehiscence and incisional hernia in the group with additional sutures (n=8/147 (5.4%)) compared with a running suture alone (n=24/148 (16%)), which correlates with a reduction of 65%.¹² Based on these findings, a sample size of 101 patients per treatment group is required to ensure a power of 80% at a two-sided significance level of 5%. To compensate potential drop-outs, a rate of 10% was added to each treatment group. This leads to a total number of 222 patients to be enrolled, respectively, 111 patients per treatment group.

Data collection

All data will be documented in standardised hard copy case report forms (CRFs). The completed CRFs will be reviewed by one of the investigators or an authorised subinvestigator. All data collected according to the study protocol will be manually transferred from the CRFs to an electronic SPSS file (version 27, IBM). Regular reviews of the correct data transfer are conducted by assessors at the study site. The electronic data will be stored in a protected folder on a server at University Hospital Augsburg. Paper-based data are stored in a locked office at the study site.

Pseudonymisation

Data are assessed and analysed in pseudonymised form. For this purpose, a randomly generated numerical

four-digit code is assigned to each participant. Access to the original data and the pseudonymisation lists is restricted to the staff of the Department of General-Visceral and Transplant Surgery at the University Hospital Augsburg. The data will be deleted as soon as they are no longer used for research.

Data analysis plan

In order to include drop-outs and patients secondary excluded because of relaparotomy within 30 days after operation and death, an intention-to-treat (ITT) and per-protocol analysis will be performed. The ITT analysis will include all participants in the group which they were randomised. We will perform sensitivity analyses to assess the effect of missing data and drop-outs. Therefore, we will perform the best-case and worst-case scenario as well as group averages. For patients missing in the 30-day or 1-year follow-up, we will use the approach of 'last observation carried further'. Baseline characteristics and last observation parameters will be assessed, to understand what the potential outcomes were.

Continuous data will be presented as mean±SD or median with IQR, depending on distribution. Categorical data will be presented as numbers with percentages. Approximately normally distributed continuous variables will be compared using the independent t-test. Non-normally distributed continuous variables will be compared using the Mann-Whitney-U test. Categorical data will be compared using the χ^2 test. Fisher's exact test will be used for categorical data if the requirements for χ^2 test are not met. A two-sided $p < 0.05$ is considered significant. Confirmatory analysis of the primary endpoint will be performed with multivariate analysis including all risk factors with a potential association with fascial dehiscence ($p < 0.15$).

Patient and public involvement statement

No patient involved.

Ethics approval and dissemination

The study protocol, the patient information and the informed consent form have been approved by the ethics committee of the Ludwig-Maximilians-University, Munich, Germany (reference number: 20-1041).

We plan to publish the findings in peer-reviewed journals and share our findings at academic conferences.

Trial registration and trial status

A WHO Universal Trial Number (U1111-1259-1956) has been obtained. The trial has been prospectively registered at the German Clinical Trials Register (DRKS00024802). The trial is currently open for recruitment. After 6 months, a total of 48 patients have been randomised at the date of submission of this paper.

DISCUSSION

Over the past years, the best technique for closure of the abdominal fascia has been extensively discussed.

Nevertheless, complications like wound infections, burst abdomen and incisional hernias are still common. There is sufficient evidence for closure of the fascia in the context of elective surgeries by prospective trials and meta-analyses,^{21 22} leading to strong recommendations how to close the fascia in this setting. The last guideline of the European hernia society from 2015 recommends for elective midline incisions, to perform a continuous suturing technique using a slowly absorbable monofilament suture in a single layer aponeurotic closure technique. The closure should be done in a small bites technique with a suture to wound length ratio at least 4/1.⁷ Against this, there is only few and heterogeneous data concerning closure of midline incision after emergency laparotomy. There are new prospective trials on continuous versus interrupted abdominal wall closure in the context of emergency surgery, but results are still missing.²³ It is widely known that emergency surgery is a risk factor for wound infections and fascia dehiscence leading to prolonged hospitalisation and a threefold higher risk of reoperation.^{10 11 24}

Some studies tried to cope with this risk factors for healing of the abdominal fascia by using additional retention sutures. These sutures are performed by stitches through the skin, subcutaneous tissue, rectus muscle and abdominal fascia and try to reduce tension on the running fascia suture.^{12 25 26} Although reduced rates of fascia dehiscence after the use of retention sutures could be shown, these full-thickness sutures never became popular in daily routine because of negative side effects like skin maceration and especially wound pain.^{12 15}

In order to find the best closure-technique for emergency midline laparotomies, further prospective trials are urgently needed. This RCT compares the most common closure technique of the abdominal fascia, the continuous suturing technique using a slowly absorbable monofilament suture in a small bites technique (two MonoMax loops), with the same technique in combination with single stitch retentions sutures (Vicryl 2 suture). To avoid the described complications—especially wound pain—these sutures do not include the whole abdominal wall but rather confine only on the fascial layer. These stitches are also made in wider distance to the fascia edge to prevent interference with the continuous fascia suture. As the combined primary endpoint, the incidence of burst abdomen by 30 days or incisional hernia within 12 months after surgery was chosen to assess the influence of both suturing techniques on the fascia healing in the emergency setting. Theoretically, a running suture and additional retention sutures combine the advantages of both suturing techniques. It is well known that one of the main risk factors for incisional hernias is postoperative surgical site infection.²⁷ The interrupted sutures could prevent a dehiscence of the fascial layer although if the continuous suture loosens up due to local tissue infection or poor fascia conditions in the emergency setting. For this purpose, a rapidly absorbable suture can secure this early phase after surgery, which is crucial for incisional hernias. The only disadvantage of additional interrupted

sutures is that the insertion of additional suture material could cause pain or suture granulomas. Therefore, we use rapid absorbable sutures to minimise this risk in the long term. It must be mentioned that fascial closure with rapid absorbable sutures alone is not recommended anymore because of high rates of incisional hernias.²¹ Thus, rapid absorbable Vicryl sutures are only used as a supplement to the main closure technique in this trial with the advantages in respect to wound pain and granulomas shown above.

The pooled primary endpoint has the advantage of evaluating the effect of different suture techniques on both the rate of burst abdomen and incisional hernias. Furthermore, it is associated with a realistic case number for study implementation. A disadvantage of this could be an under-reporting of a difference in the incidence of burst abdomen, which is rather low compared with the rate of incisional hernias.

In summary, the CONIAC trial will assess efficacy and safety of two different abdominal wall closure techniques in patients undergoing emergency midline laparotomy. The results of this trial will help to improve short-term and long-term surgical outcomes and will hopefully provide further evidence to find the optimal closure technique of the abdominal fascia in the emergency setting.

Contributors SW, LAdG, DV and MA designed the study protocol. MCS, DV and SW developed the evaluation plan. SW drafted the initial manuscript. MCS, DV, FS and MA critically revised the manuscript for important intellectual content. Final approval of the version to be published was given by all authors. DV, SW and MA took responsibility for the work and controlled the decision to publish. The corresponding author attests that all listed authors meet the authorship criteria and that no others meeting the criteria have been omitted.

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Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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