



Glucocorticoids for acute urticaria: study protocol for a double-blind non-inferiority randomised controlled trial

Submitted by Stéphanie Pinot on Wed, 10/02/2019 - 16:29

Titre	Glucocorticoids for acute urticaria: study protocol for a double-blind non-inferiority randomised controlled trial
Type de publication	Article de revue
Auteur	Javaud, Nicolas [1], Soria, Angele [2], Maignan, Maxime [3], Martin, Ludovic [4], Descamps, Vincent [5], Fain, Olivier [6], Bouillet, Laurence [7], Berard, Frédéric [8], Tazarourte, Karim [9], Roy, Pierre-Marie [10], Fontaine, Jean-Paul [11], Bagot, Martine [12], Khellaf, Mehdi [13], Goulet, Helene [14], Lapostolle, Frederic [15], Casalino, Enrique [16], Doutre, Marie-Sylvie [17], Gil-Jardine, Cedric [18], Caux, Frederic [19], Chosidow, Olivier [20], Pateron, Dominique [21], Vicaut, Eric [22], Adnet, Frederic [23]
Editeur	BMJ Publishing
Type	Article scientifique dans une revue à comité de lecture
Année	2019
Langue	Anglais
Date	21 Août 2019
Pagination	e027431
Volume	9
Titre de la revue	BMJ Open
ISSN	2044-6055

Résumé en anglais

INTRODUCTION: This study protocol describes a trial designed to investigate whether antihistamine alone in patients with acute urticaria does not increase the 7-day Urticaria Activity Score (UAS7) in comparison with an association of antihistamine and glucocorticoids and reduces short-term relapses and chronic-induced urticaria.

METHODS AND ANALYSIS: This is a prospective, double-blind, parallel-group, multicentre non-inferiority randomised controlled trial. Two-hundred and forty patients with acute urticaria admitted to emergency department will be randomised in a 1:1 ratio to receive levocetirizine or an association of levocetirizine and prednisone. Randomisation will be stratified by centre. The primary outcome will be the UAS7 at day 7. The secondary outcomes will encompass recurrence of hives and/or itch at day 7; occurrence of spontaneous hives or itch for >6 weeks; patients with angioedema at day 7, and 2, 6, 12 and 24 weeks; new emergency visits for acute urticaria recurrences at days 7 and 14, and 3 months; Dermatology Life Quality Index at days 7 and 14, and 3 and 6 months; and Chronic Urticaria Quality of Life Questionnaire at 6 weeks.

ETHICS AND DISSEMINATION: The protocol has been approved by the and will be carried out in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. A steering committee will oversee the progress of the study. Findings will be disseminated through national and international scientific conferences and publication in peer-reviewed journals.

TRIAL REGISTRATION NUMBER: NCT03545464.

URL de la notice	http://okina.univ-angers.fr/publications/ua20297 [24]
DOI	10.1136/bmjopen-2018-027431 [25]
Lien vers le document	https://bmjopen.bmj.com/content/9/8/e027431.info [26]
Autre titre	BMJ Open
Identifiant (ID) PubMed	31439599 [27]

Liens

- [1] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=31653>
- [2] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39748>
- [3] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=31739>
- [4] <http://okina.univ-angers.fr/ludovic.martin/publications>
- [5] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39749>
- [6] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=30279>
- [7] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=31654>
- [8] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=33846>
- [9] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39750>
- [10] <http://okina.univ-angers.fr/pierremarie.roy/publications>
- [11] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39751>
- [12] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39752>
- [13] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39753>
- [14] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39754>
- [15] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=31657>
- [16] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39755>
- [17] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39756>
- [18] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39757>
- [19] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39758>
- [20] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39759>
- [21] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=39760>
- [22] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=30269>
- [23] <http://okina.univ-angers.fr/publications?f%5Bauthor%5D=31659>
- [24] <http://okina.univ-angers.fr/publications/ua20297>
- [25] <http://dx.doi.org/10.1136/bmjopen-2018-027431>
- [26] <https://bmjopen.bmj.com/content/9/8/e027431.info>
- [27] <http://www.ncbi.nlm.nih.gov/pubmed/31439599?dopt=Abstract>

Publié sur *Okina* (<http://okina.univ-angers.fr>)