Universität Basel

Publication

Canakinumab Lacks Efficacy in Treating Adult Patients with Moderate to Severe Chronic Spontaneous Urticaria in a Phase II Randomized Double-Blind Placebo-Controlled Single-Center Study

JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

ID 4611804
Author(s) Maul, Julia-Tatjana; Distler, Meike; Kolios, Antonios; Maul, Lara Valeska; Guillet, Carole; Graf, Nicole; Imhof, Laurence; Lang, Claudia; Navarini, Alexander A.; Schmid-Grendelmeier, Peter
Author(s) at UniBasel Navarini, Alexander ;
Year 2021
Title Canakinumab Lacks Efficacy in Treating Adult Patients with Moderate to Severe Chronic Spontaneous Urticaria in a Phase II Randomized Double-Blind Placebo-Controlled Single-Center Study
Journal The Journal of Allergy and Clinical Immunology: In Practice
Volume 9
Number 1
Pages / Article-Number 463-468.e3
Keywords Canakinumab; IL-1β antagonist; Treatment; Urticaria
Chronic idiopathic/spontaneous urticaria (CSU) is a common disease with a significant proportion of patients who do not respond to standard therapy with antihistamines and optionally corticosteroids/immunosuppressants.; The IL-1β antagonist canakinumab is effective in cryopyrin-associated periodic syndromes associated with urticarial symptoms and urticarial vasculitis, and so it was suspected that it could also be effective in patients with CSU.; The effect of canakinumab was investigated in 20 patients with moderate to severe CSU in a 1:1 randomization to either canakinumab or placebo in a double-blind single-dose crossover design. The verum group received 150 mg canakinumab subcutaneously once at baseline. Patients who had received placebo were able to switch to canakinumab at week 4 if they did not improve. The primary end point was clinical improvement at week 4 compared with baseline in sum of urticaria activity scores over 7 consecutive days. Secondary end points were the clinical improvement at week 8 compared with baseline in sum of urticaria activity scores over 7 consecutive days and the clinical improvement measured by the Physician Score and Dermatology Life Quality Index at week 1, 2, 4, and 8.; At week 4, 2 patients with canakinumab and 3 with placebo met the primary end point, and so canakinumab failed the significant superiority to the placebo (P = 1.0). An inclusion of the patients who switched to canakinumab after 4 weeks did not alter the result. There was also no significant difference between the verum and placebo groups for all secondary end points. The therapy was well tolerated, and mild adverse events were equally distributed between verum and placebo groups.; Because of this clinical trial with 20 patients, it must be assumed that canakinumab has no effect on lesions of CSU. This suggests that IL-1β may not play a crucial role in pathology of patients with CSU, unlike, for example, in hereditary fevers or urticarial vasculitis, where targeting IL-1 is a main treatment option. However, the good tolerability of canakinumab could be confirmed.
Publisher Elsevier
ISSN/ISBN 2213-2201
edoc-URL https://edoc.unibas.ch/80455/
Full Text on edoc No;
Digital Object Identifier DOI 10.1016/j.jaip.2020.07.058
PubMed ID http://www.ncbi.nlm.nih.gov/pubmed/32827729

Document type (ISI) Journal Article