KCE17007 – PELICAN STUDY

SYNOPSIS PRELIMINARY RESULTS

FULL TITLE OF THE TRIAL

Safety, efficacy, and patient acceptability of topical treatment versus systemic treatment: a randomized, multicenter, comparative pragmatic trial in adult patients suffering from diverse localized neuropathic pain (LNP) syndromes.

SHORT STUDY TITLE / ACRONYM

Localized neuropathic pain: topical treatment versus systemic treatment.

PELICAN (**P**r**E**gabalin**LI**docaine**CA**psaicin**N**europathicpain)

RESEARCH REFERENCE NUMBERS

Clinicaltrials.gov Number : NCT03348735
EUDRACT Number : 2018-003617-17

The manuscript of this study is currently in the preparation for submission. As soon as the pubmication is available, it will be published on the KCE Trials webpage.

Below is a summary of the study with the preliminary results.

Sponsor	University Hospital Antwerp (UZA) Multidisciplinary Pain Center (PCT)
Chief Investigator	Prof. Dr. Guy Hans
Study centers	UZA, UZ Leuven, UZ Brussel, UZ Gent, AZ Delta, UVC Brugmann, Grand Hôpital de Charleroi (GHdC), AZ Turnhout, AZ Klina, AZ Sint-Jan Brugge, Ziekenhuis Oost-Limburg (ZOL) Genk, Hôpital Universitaire Sart Tilman de Liège, AZ Monica, Hôpital Universitaire Saint Luc (UCL), CHU-UCL Namur (Mont-Godinne & Ste.-Elisabeth)
Publication	Submission in Q3 – 2022
Study period	29/10/2018 – 05/03/2020
Objectives	Determine if topical treatment significantly improves health-related quality of life compared to systemic treatment, in adult patients suffering from localized neuropathic pain across a wide variety of etiologies (LNP)
Methodology	Randomized 1:1:1, multicenter, comparative pragmatic trial
Interventions	Topical treatment 1: lidocaine 5% medicated plaster (Versatis) Topical treatment 2: capsaicin 8% patch (Qutenza) Systemic treatment: pregabalin (generics)
Number of patients planned	591
Number of patients randomised	32 adult patients included in the final analysis report (study was terminated prematurely due to lower recruitment than expected)
Diagnosis and main	Suffering from localized neuropathic pain with a circumscribed painful area not larger than 520 cm^2
Criteria for inclusion	Localized neuropathic pain condition with a duration between 1 and max. 24 months (initially max. duration of 12 months, but this was changed in v5.0 of the protocol, to enhance recruitment) and related to known aetiology
Assessments	A specialized digital assessment system was developed for this study (PELICAN@Home platform). The assessments were also available on paper for patients who did not have access to computer or tablet
EC approval	Final amendment February 11, 2020, containing Informed Consent Form Version 7.0_03/01/2020 and Protocol Version 5.0_20/01/2020

DSUR	Published on 22 December 2020
Study website	www.uza.be/pelican-studie and patient brochures in Dutch, French and German language were printed
TSC meetings	Organised on June 17, 2019 and December 12, 2019
Qualitative research	Performed after the comparative trial was stopped due to lasting recruitment problems. Consisted of two parts: (1) SurveyMonkey based questionnaire (25 questions), followed by (2) in-depth one to one synchronous interviews (videoconference) with the Principal Investigator (PI) from participating centers, to identify and evaluate reasons for recruitment failure.
General conclusion	Despite the recruitment failure of the pragmatic trial that led to a premature discontinuation of the PELICAN study, some valuable lessons can be learned from the collected data and the following qualitative review. Although a limited number of patients was recruited, the societal details correspond to previous studies. This can be regarded as a confirmation of the validity of the study protocol and the applied inclusion process. Based on the feedback gathered from the participating pain centers during the trial but also from the qualitative study some crucial reasons for the recruitment failure became apparent. These should be subdivided into study-related causes and more general causes related to the organisation of pain management at a national level