Results for trial EudraCT no. 2020-000042-34

Study title: "PROOF OF CONCEPT STUDY ON LTX-109 AS TREATMENT FOR HIDRADENITIS SUPPURATIVA"

In trial C20-109-07/EudraCT no. 2020-000042-34, a single-center, open label proof-of-concept study, the investigational medicinal product, LTX-109 3% w/w gel, was administrated twice daily (morning- evening) on active hidradenitis lesions during the intervention period of six (6) weeks. 16 patients were planned to be enrolled, and the actual enrollment was 11 patients.

Study period

First subject enrolled: 15MAR2021, Last subject completed: 15JUN2021

Study Objectives

To assess if percutaneous application of LTX-109 in a gel vehicle is a safe treatment of Hidradenitis suppurativa and to identify clinical response to intervention, as well to identify if covariates such as age, disease duration, smoking state and BMI influence patient reported measures.

Efficacy results

At the aggregate level, the results show that the average number of boils was not reduced during the 6 weeks of treatment. On average, the results show no change in the experience of pain in the boils during the 6 weeks of treatment.

On average, the results show a marginal, but not significant, reduction in the perception of total pain during the 6 weeks of treatment. On average, the results show a significant reduction in the number of infected boils during the 6 weeks of treatment.

The "Sum Score" results show no significant patient improvement after 6 weeks of treatment with LTX-109.

Safety results

No Serious Adverse Reactions (SARs) occurred in this study. Twice daily percutaneous administration of LTX-109 (3%) on active hidradenitis lesions over 6 weeks was considered to have an acceptable safety profile although some of the patients experienced some short-term discomfort associated with the use of LTX-109 in lesions.

Conclusions

The study concluded that:

- percutaneous administration of LTX-109 (3%) was considered safe, albeit some patients experienced some short-term discomfort associated with the use of LTX-109 in lesions and
- the treatment with LTX-109, despite significant reduction in bacterial infections, proved to show only marginal patient improvement by reducing the number of infected noduli.