1. Clinical trial identification

Researchers look at the results of many studies to decide which drugs work best and are safest for patients. It takes participants in many studies all around the world to advance medical science. This summary only shows the results from this one study. Other studies may find different results.

1.1. Title of the trial

Non-interventional Study in Allergic Patients Suffering from Grass Pollen Induced Rhinitis/ Rhinoconjunctivitis with or without Asthma.
Retrospective Assessment of the Efficacy of a Pre-seasonal Specific Immunotherapy on the Allergy Symptoms / Disease Activity during the Pollen Season

1.2. Protocol number

Depigoid Phleum – PRO 2013

1.3. EU trial number

EudraCT 2013-004920-12

2. Name and contact of sponsor

LETI Pharma GmbH, Stockumer Str. 28, 58453 Witten, Germany
Phone +49 2302 202860

3. General information about clinical trial

3.1 Where the trial was conducted

Overall 38 study sites in Germany, Poland and in the Czech Republic participated in this NIS for retrospective collection of patient outcome reports.

3.2 When the trial was conducted (start & stop dates)

Period for collection of data: October - December 2013
Per patient: approx. 15 - 20 min

3.3. The main objectives of the trial and explanation of the reasons for conducting it

Patient Reported Outcome (PRO) on the disease activity, intensity of allergic symptoms, intake of rescue medication and global assessment during the pollen season 2013 after 5 – 6 months of treatment with 4 different doses of Depigoid Phleum: 100, 1000, 5000 or 10000 DPP/ml.

4. Population of subjects

4.1. The number of subjects included in the trial

Altogether 38 study sites in the Czech Republic, Germany and Poland enrolled 184 Patients into this NIS.

4.2. Age groups and gender breakdown

The demographic data were raised as follows:
Age: The age of all patients ranged from 19 to 70 years with a mean of 34.02 years.
Gender: 184 Patients, 89 female patients (48.4%) and 95 male patients (51.6%)

4.3. Inclusion and exclusion criteria

Inclusion Criteria:

Participating patients had to fulfil all of the following inclusion criteria:

1. Written informed consent.
2. Allergic rhinitis/rhinoconjunctivitis with or without concomitant asthma due to grass pollen allergy.
3. Treatment with one of 4 concentrations of Depigoid Phleum (100, 1000, 5000 and 10000 DPP/ml) in the period from October 2012 until April 2013.

Exclusion Criteria:

1. Patients presenting the following exclusion criterion were not included in the study:
2. Less than 4 applications of 0.5 ml of one of 4 concentrations of Depigoid Phleum (100, 1000, 5000 and 10000 DPP/ml) between October 2012 and April 2013.

5. Investigational medicinal products used

n.a.

6. Description of adverse reactions and their frequency

n.a.

7. Overall results of the clinical trials

Depigoid Phleum PRO-2013 was a non-interventional study which aimed to obtain retrospective data of allergic patients suffering from grass pollen induced rhinitis or rhinoconjunctivitis with or without asthma. The purpose of this NIS was to support by clinical outcome the dose-response relationship of of 4 different doses of Depigoid Phleum: 100, 1000, 5000 or 10000 DPP/ml assessed by 184 patients during the pollen season 2013 after 5 – 6 months of pre-seasonal treatment.

Therefore, the objective of this NIS was the patient reported outcome on the disease activity, intensity of allergic symptoms, intake of rescue medication and global assessment assessed by a patient questionnaire.

The combined SMS regarding rhinitis/ rhinoconjunctivitis symptoms was lowest for the 1000 DPP/ml group with a median score of 8.0. However, a statistically significant difference to the 100 DPP/ml group was missed (10.0; p = 0.0513).

In addition, the combined SMS was also low for the 10000 DPP/ml group (9.0).

The combined SMS regarding lung symptoms, median scores were lowest again for both, the 1000 DPP/ml and 10000 DPP/ml group (8.5 and 9.3), without statistically significant differences to the 100 DPP/ml group (10.0).

Regarding the SS for rhinitis/ rhinoconjunctivitis, median scores were equal for the three active dose groups 1000, 5000 and 10000 DPP/ml with 6.0 and highest again for the 100 DPP/ml group (7.0). Regarding the SS for lung symptoms, a slight dose-response relationship could be observed with lowest median SS in the 10000 DPP/ml and highest in the 100 DPP/ml group (6.0 vs 8.0) without reaching statistical significance.

The RMS regarding rhinitis/ rhinoconjunctivitis and lung symptoms was lowest for the 1000 DPP/ml group with a median score of 1.5. Here, the difference to the 100 DPP/ml group was statistically significant with p = 0.0387. Notably, the highest score was found for the 10000 DPP/ml group (median: 3.0).

Apart from these results, also the analyses on disease activity failed to show a clear dose-response in favour of one of the three active doses:

Patients' perception of disease activity during the grass pollen season 2013 was assessed by means of a VAS, ranging from "not present" to "extremely active".

During the pollen season, disease activity was lowest for the 1000 DPP/ml group and 10000 DPP/ml group (median 2.6 and 2.7 cm, respectively). For both groups, the difference compared to the 100 DPP/ml group (3.8) was statistically significant with p = 0.0375 and p = 0.0301, respectively.

Accordingly, the highest change in disease activity was found for the 1000 DPP/ml group with a median change of -4.3. When compared to the 100 DPP/ml group, the difference was statistically significant with p = 0.0288. The change was similar for the 10000 DPP/ml group with a median change of -4.0 (p = 0.0377).

Similar to the results assessed by the VAS, also patients' global assessment showed best improvement for both, the 1000 DPP/ml and 10000 DPP/ml group.

For the 1000 DPP/ml group, 62.5% of the patients (30 out of 48) rated the efficacy of therapy as "positive". 7 patients (14.6%) rated efficacy as "excellent" and 23 patients (47.9%) as "good"; only 1 patient (2.1%) rated efficacy as "unacceptable".

Also, for the 10000 DPP/ml group, the global assessment was superior compared to the overall population: 8 out of 40 patients (20.0%) rated the efficacy of therapy as "excellent" and 50.0% as "good". No patient in this group assessed the efficacy as "unaccepatable". When classified into the two categories "positive" and "negative", 70% of the patients rated the efficacy as "positive".

Most negative results were found for the 100 DPP/ml group, where only 25 patients (53.2%) rated the efficacy of therapy as "positive". In addition, only 2 patients (4.3%) rated the efficacy as "excellent".

8. Comments on the outcome of the clinical trial

Overall, as expected, the results obtained during this NIS clearly showed worst improvement for patients included in the 100 DPP/ml dose group, which served as pseudo-placebo. Regrettable, on the other hand, no clear dose-response relationship could be shown with regard to the three active doses 1000, 5000 and 10000 DPP/ml.

Taken together, most favourable results were obtained for both, the 1000 and 10000 DPP/ml group, with similar values found for all parameters assessed.

9. Indication if follow up clinical trials are foreseen

No follow-up trial for this NIS planned