

Korneuburg, 24.05.2022

Dear EMA Service Desk Team,

Regarding "EudraCT 2009-009379-36", start date of the trial was 22.04.2009 and the end date of the trial was 16.05.2009. The date for final report is 31.05.2010.

Sponsor code: 281015BS

The title of study: A phase II, single-center, randomized, controlled, observer-blind study with intra-individual comparisons within two parallel groups to assess the efficacy of a topical Aescin formulation in the treatment of allergic contact dermatitis

Below is the efficacy result for this study:

Efficacy Conclusions

During the analysis of the study, the sponsor and the CRO were faced with difficulties on interpretation of study data. The study duration was very short and the GCP compliant study conduct was supervised with two monitoring visits followed by an audit to assess the reliability of dose compliance and validity of study measurements. Corrective and preventive actions have been agreed and were implemented to reach unambiguous results in the future. However, the interpretation of the results of this study remains contradictory.

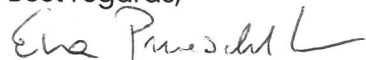
Primary endpoint: A statistical analysis was performed according to the statistical analysis plan. However, the results were not interpreted.

Secondary endpoints: A statistical analysis was performed according to the statistical analysis plan. However, the results were not interpreted.

Therefore, no efficacy conclusions were drawn.

We are writing this attachment in order to submit the mentioned study as soon as possible.

Best regards,

A handwritten signature in black ink, appearing to read "Eva Prieschl-Grassauer".

Dr. Eva Prieschl-Grassauer

CSO