Prematurely ended – statement

28.03.2023

EudraCT number: 2012-001352-19

Full title of the study: BE-RELACs-Trial: Biomarkers Explaining RELevance of ACute Rejections

Study Contact: Center for Clinical Trials

Sponsor: Hannover Medical School / Medizinische Hochschule Hannover (MHH)

Contact email address: EudraCT@mh-hannover.de

Product(s): Nulojix R

Date of the early termination of the trial: there is no termination date

Statement on discontinuation of the study: Trial status "completed" is unclear, "prematurely ended" would be appropriate;

Summary - Conclusions

Efficacy results:
The study has been stopped after 2 patients have been recruited (one to the Belatacept and one to the Cyclosporine arm). Neither Biomarkers, nor clinical parameters can be reasonable analyzed.

Safety results:
One serious adverse event had been recorded (Cyclosporine, urogenital tract infection). The patient completely recovered.

Conclusion:
This report briefly describes the patients, documents adverse events as recorded in the trial and sketches laboratory findings. Both patients passed study treatment and investigations without problems and had been put on standard medication successfully.

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