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To
Sponsor

Hamburg, 29.9.2021

EudraCT-No.: 2012-004807-10

Study title: Relapse Escalation treatment trial in Optic Neuritis (RESCON)

Multi-centre RCT to study the efficacy of plasma exchange (PE) as an escalation treatment strategy in steroid-unresponsive Optic Neuritis

Statement of the Coordinating Investigator

As part of the RESCON trial patients with optic neuritis that presented a visual acuity less than 0.7 on one eye after treatment with high-dose steroids at least 7 days prior to randomization should be randomized to two different treatment options (ultrahigh-dose steroid treatment or 5 cycles of plasma exchange).

The RESCON trial was terminated prematurely due to low recruitment in participating trial sites. Despite great efforts in Hamburg, where finally 8 patients had been enrolled (all in Hamburg), the recruitment of 40 patients could not be achieved.

The main problem for low recruitment was modest ambition of centers and difficulties in interaction of neurologists and ophthalmologists in participating centers and problems to manage study necessities under pressure of timelines within the study.

Due to the low recruitment and early termination no efficacy analysis was feasible and no robust and statistically analysable data regarding the safety of the therapy were generated. Therefore, no scientific reliable conclusion can be drawn. The need of this study remains.

Prof. Dr. C. Heesen