

Hamburg, 04.02.2022

EudraCT-Nr.: 2016-001166-29

Pfplan-Nr.: nims-009

Title of the clinical study

A randomised controlled trial to compare ocrelizumab or alemtuzumab with autologous Hematopoietic Stem Cell Transplantation (aHSCT) in high inflammatory Multiple Sclerosis (COAST)

Sponsor

University Medical Centre Hamburg-Eppendorf, represented by the Board of the Medical Faculty, Martinistr. 52, 20246 Hamburg. Representative of the sponsor and LKP: Prof. Dr. med. Nicolaus Kröger

Statement of the sponsor on the premature termination of the study

The present study was evaluated positively by the responsible ethics committee in September 2019 and approved by the PEI in June 2020. After an interruption in preparations due to the pandemic, the first centre at the UKE (Interdisciplinary Clinic for Stem Cell Transplantation and Multiple Sclerosis Day Clinic and Outpatient Clinic, Neurological Polyclinic) was initiated on 27. August 2021. At three centres in Germany, 50 patients (1:1) were to be included in this multicentre study within 2 years.

The first randomised patient had to discontinue the study before the first treatment for personal reasons. Since then, no new patients could be included in the study. Potentially suitable patients showed interest in stem cell transplantation in the preliminary interview and little acceptance for the possible randomisation into the control group (antibodies).

An assessment of the recruitment possibilities by the LKP and the Co-PI Prof. Dr. Christoph Heesen led to the decision to stop the study at this early stage.

In this study, no therapeutic intervention was carried out in any of the study arms.

Prof. Dr. N. Kröger

Prof. Dr. Chr. Heesen