Prematurely ended-statement

EudraCT number	2011-004787-30
Full title of the study	Modification of the visual outcome after optic neuritis in CIS or MS by Gilenya®
Sponsor ID	MOVING
Sponsor	Charité - Universitätsmedizin Berlin Charitéplatz 1, 10117 Berlin
Study Contact	Prof. Dr. Friedemann Paul NeuroCure Clinical Research Center NCRC ECRC AG Klinische Neuroimmunologie Charitéplatz 1, 10117 Berlin
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Product	Fingolimod 0.5 mg (Gilenya©, Novartis) Interferon Beta-1b 250 µg
Date of the early termination of the trial	04/APR/2016
Statement on discontinuation of the study	Study prematurely ended due to lack of recruitment. Only 8 of 88 planned patients were included in the trial. Statistical evaluation was performed on an exploratory level only. Due to the difficulty in recruiting suitable participants, the intended recruitment end date was initially extended from Q2/2014 to Q2/2016. Nevertheless, due to the narrow time window for study inclusion after the qualifying event (optic neuritis), recruitment for the study turned out to be considerably more difficult than expected. Therefore, it was not foreseeable to reach the targeted case number of 88 patients in a realistic time, so that the study had to be terminated prematurely.
Publication	Fingolimod after a first unilateral episode of acute optic neuritis (MOVING) - preliminary results from a randomized, rater-blind, active-controlled, phase 2 trial. Albert C, Mikolajczak J, Liekfeld A, Piper SK, Scheel M, Zimmermann HG, Nowak C, Dörr J, Bellmann-Strobl J, Chien C, Brandt AU, Paul F, Hoffmann O. BMC Neurol. 2020 Mar 3;20(1):75. doi: 10.1186/s12883-020-01645-z.

Signature Prof. Dr. Friedemann Paul
Job role Sponsor representative