

**Prematurely ended-statement**

EudraCT number	2012-000411-91
Full title of the study	<b>Monitoring natural killer cells in multiple sclerosis patients treated with fingolimod: a monocentric, prospective, one year, baseline-to-treatment, open-label trial</b>
Protocol Code	<b>NKZellen-Version1.0</b>
Sponsor	Charité – Universitätsmedizin Berlin
Sponsor representative	PD Dr. med. Jan-Markus Dörr NeuroCure Clinical Research Center NCRC AG Klinische Neuroimmunologie Charitéplatz 1, 10117 Berlin
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Product	Fingolimod (Gilenya®)
Date of the early termination of the trial	03 – Aug – 2018
Statement on discontinuation of the study	<p>The reason for the early termination was the significantly delayed recruitment of suitable participants. In the originally planned 19-month period, only 9 patients could be included. Even the extension of the recruitment period to 48 months did not lead to the originally planned 40 patients. A further extension of the recruitment period was not promising.</p> <p>The main reason for the slow recruitment was the increasing diversification of multiple sclerosis (MS) therapies. Since the study was designed, five new drugs had been approved for the treatment of MS, predominantly in the indication of highly active MS, which competed with the investigational drug. Another reason was the increasing oversaturation of the MS treatment market with clinical trials, observational studies, etc., leading to a decrease in willingness to participate in trials on the part of patients. A total of 21 participants were included. The data analysis is performed as planned and described in the protocol.</p>

**Signature** PD Dr. med. Jan-Markus Dörr  
**Job role** Sponsor representative / Principal Investigator