Universitätsklinikum Tübingen

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05.11.2020

Prematurely ended -statement

EudraCT number: 2016-001611-20

Full title of the study: Pathophysiologie-basierte Therapie von Patienten mit epileptischen Enzephalopathien

Study Contact: Sarah Rau

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Product: Phenytoin, Lacosamid

Date of the early termination of the trial: 03/Jan/2020

Statement on discontinuation of the study: Study prematurely ended due to lack of enrolled patients. Seven patients were screened based on the inclusion criteria. Unfortunately, none of the patients were able to be included, either due to not meeting the inclusion criteria or lack of parent's consent. The main factor was the primary design as a single-site study. Several patients were unwilling to be transferred to Tübingen in order to participate in the

study. The number of potential patients able to be screened for the study was also too limited for the planned recruitment phase. The question posed by the study remains of highest clinical interest. A new study would have to be carried out as a multicenter study.

S Rau

Sarah Rau
Study Coordinator