

Prematurely ended-statement

EudraCT number	2011-001403-12
Full title of the study	Carbon Dioxide for the Treatment of Febrile Seizures
Sponsor ID	CARDIF
Sponsor	Charité - Universitätsmedizin Berlin, Charitéplatz 1, 10117 Berlin
Study Contact	Prof. Dr. med. Markus Schülke-Gerstenfeld Charité – Universitätsmedizin Berlin Klinik für Pädiatrie m. S. Neurologie Augustenburger Platz 1 13353 Berlin
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Product	Verum: Carbogen Placebo: Oxygen
Date of the early termination of the trial	2015/06/30
Statement on discontinuation of the study	<p>The study was prematurely ended due to futility.</p> <p>In the interim analysis of the CARDIF study results were unexpectedly found in favor of an inferiority of the verum compound. For this reason the study had to be aborted ("stopping for futility").</p> <p>In the following, the results are summarized.</p> <p>Placebo and verum were given in 10 patients each. A successful outcome (cessation of seizure) was observed 7 times with placebo and 2 times with verum. The validation of the study shows to a p-value of 0.07 in the two-sided Fisher's exact test and a p-value of 0.035 in the one-sided Fisher's exact test in favor of placebo. Thus, the formal criterion $p > 0.3$ (unilateral superiority of verum) is fulfilled and the study must be stopped.</p> <p>In addition, five patients were analyzed by crossover with three discordant couples: 2 times in favor of placebo, once in favor of verum. Significance testing is useless due to the low number of cases; the results do not contradict with the results of the primary analysis. Overall, these results lead to the fact that the study must be stopped due to ethical and statistical reasons.</p>

	The study medication was given only in case of a febrile seizure. There is no risk for the patients, but also no benefit according to the interim analysis.
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Signature Prof. Dr. Markus Schülke-Gerstenfeld

Job role Sponsor Representative

[Hier eingeben]