

End of Study report

I General information	
EudraCT number	2009-016080-11
NL number	NL29951.029.10
Title: <i>A COMPREHENSIVE AND TARGETED THERAPY APPROACH IN PEDIATRIC MALIGNANT PONTINE GLIOMAS</i>	
Sponsor	VU University Medical Center
Participating sites	<input checked="" type="checkbox"/> singlecenter:
	<input type="checkbox"/> multicenter, national
Principal Investigator	Prof. dr. G.J.L. Kaspers

II Study status	
<input type="checkbox"/> Terminated as planned	End date of study:
<input checked="" type="checkbox"/> Early Termination	End date early termination: 01-06-2018
Reason for early termination: <i>Halfway during the trial, pediatric oncology care in the Netherlands was centralized at the Princess Máxima Center in Utrecht. Due to an initial slow inclusion rate in a non-centralized setting at the Amsterdam UMC, location VUmc and later logistic difficulties transferring the trial to the Princess Máxima Center.</i>	
How many participants were included at the time it was decided to terminate the study early? What are the consequences for these participants? <i>9 Patients were included and enrolled in the first 2 dose cohort. All study treatments and assessments were already conducted. The study was terminated before enrollment of patients the third dose cohort. There were no consequences for participants.</i>	
What are the consequences of the early termination for the study results? <i>This study had to be terminated prematurely before we could escalate to the final dose cohort(s) prescribing also everolimus. We won't be able to answer the primary and secondary research questions of the study.</i>	

III Status inclusion	
How many participants are included in the study?	9
What is the total number of participants that needed to be included according to protocol?	12-24
What is the cause for not reaching the intended number of participants? <i>See above, reason early termination.</i>	

IV Report drafted by	
Name and function:	Prof. Dr. G.J.L. Kaspers, Head of Pediatric Oncology at VUmc and P.I.
Date report	19-11-2023
Signature	