

End of Study report

I General information	
EudraCT number	2013-002744-89
NL number	NL45527.078.13
Title: <i>Bioavailability of oral ciprofloxacin tablets and suspension in pediatric cancer patients</i>	
Sponsor	Erasmus MC
Participating sites	<input checked="" type="checkbox"/> singlecenter: Erasmus MC only
	<input type="checkbox"/> multicenter
Principal Investigator	Dr. C.M. Zwaan

II Study status	
<input type="checkbox"/> Terminated as planned	End date of study:
<input checked="" type="checkbox"/> Early Termination	End date early termination: 01-04-2016
Reason for early termination: <i>Inclusion rate too slow.</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>Two participants were included in the study; both already finished treatment at time of termination of the study.</i>	
What are the consequences of the early termination for the study results? <i>Only one patient participated for the full three study visits. The other participant terminated participation early, because he no longer fulfilled the inclusion criteria after progression of disease. No statistical analysis on these results is feasible.</i>	

III Status inclusion	
How many participants are included in the study?	Erasmus MC: 2
What is the total number of participants that needed to be included according to protocol?	Erasmus MC: 20
What is the cause for not reaching the intended number of participants? <i>Patients were too ill to participate in the study. A lot of patients developed mucositis, which was a contra-indication for participation, so they could not participate.</i>	

IV Report drafted by	
Name and function:	P. Winkler-Seinstra, Trialmanager
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