Clinical trial results:
A Single Centered, Prospective, Open-labeled, Pharmacokinetic Pilot Study of Tacrolimus Administration via Rectiole

Summary

EudraCT number	2014-002425-35
Trial protocol	NL
Global end of trial date	15 December 2017

Results information

Result version number	v1 (current)
This version publication date	20 January 2018
First version publication date	20 January 2018

Trial information

Trial identification

Sponsor protocol code	NL2014-002425-35/SpartacusBrindisi

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University Medical Center Utrecht
Sponsor organisation address	Heidelberglaan 100, Utrecht, Netherlands, 3584 CX
Public contact	M.A. Sikma, University Medical Center Utrecht, 0031 887558561, m.a.sikma@umcutrecht.nl
Scientific contact	M.A. Sikma, University Medical Center Utrecht, 0031 887558561, m.a.sikma@umcutrecht.nl

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 December 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 December 2017
Global end of trial reached?	Yes
Global end of trial date	15 December 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Bio-availability of rectal administered tacrolimus

Protection of trial subjects:

No investigational acts have been conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 11
Worldwide total number of subjects	11
EEA total number of subjects	11

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	11
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

11 patients have been recruited. They all have granted informed consent. No study procedures have been conducted.

Pre-assignment

Screening details:

11 patients have granted informed consent, no study procedures have been performed.

Pre-assignment period milestones

Number of subjects started	11
Number of subjects completed	11

Period 1

Period 1 title	inclusion period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

no blinding

Arms

Arm title	rectiole

Arm description:

There is one arm in this study. All patients would have been treated the same. No comparator group.

Arm type	Experimental
Investigational medicinal product name	tacrolimus
Investigational medicinal product code	
Other name	tacrolimus rectiole
Pharmaceutical forms	Rectal solution
Routes of administration	Enteral use

Dosage and administration details:

The starting dose via the rectiole will be 0.025 mg/kg divided in two doses per day or lower based on the whole blood tacrolimus trough concentration of day 1 equal to the intravenous dose.
No investigational activities have been conducted.

Number of subjects in period 1	rectiole
Started	11
Completed	11

Baseline characteristics

End points

End points reporting groups

Reporting group title	rectiole

Reporting group description:

There is one arm in this study. All patients would have been treated the same. No comparator group.

Primary: bioavailability of tacrolimus

End point title	bioavailability of tacrolimus[1]

End point description:

End point type	Primary

End point timeframe:

2 years

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: the study has been preliminary halted due to organisational reasons. No statistical analyses have been performed

End point values	rectiole			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: ng/ml				
median (inter-quartile range (Q1-Q3))	(to)			

Notes:

[2] - the study is preliminary halted

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Serious adverse events such as: death, prolongation of existing inpatients' hospitalization or requiring hospitalization, repeated surgery, significant disability or incapacity, wound complications, serious bleeding (> 1000 ml per day), sepsis, infection,

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Frequency threshold for reporting non-serious adverse events: 0.05 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No adverse events have occurred, because the study was preliminary halted

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 December 2017	Halt of trial: Due to organisational difficulties to produce the tacrolimus rectiole in our pharmacy, whereby the production process has been stopped. No patient has been exposed to the investigational product. No risk to the patients is therefore expected.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
15 December 2017	Halt of study, because of organisational causes.	-

Notes:

Limitations and caveats

None reported