Clinical trial results:
A 3-Armed Prospective Randomized Controlled, Open-Labeled Phase III Trial to Evaluate Late Introduction of Cyclosporine or Everolimus versus a 5-day Delay of Cyclosporine in Combination with MMF in Liver Transplant Recipients with MELD-Scores25

Summary

EudraCT number	2009-017192-26
Trial protocol	DE
Global end of trial date	28 May 2015

Results information

Result version number	v1 (current)
This version publication date	04 November 2022
First version publication date	04 November 2022
Summary attachment (see zip file)	Ergebnisbericht (Ergebnisbericht.pdf)

Trial information

Trial identification

Sponsor protocol code	BUILT_01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Clinicaltrials.gov: NCT01023542

Notes:

Sponsors

Sponsor organisation name	University Hospital Regensburg
Sponsor organisation address	Franz-Josef-Strauss-Allee 11, Regensburg, Germany, 93042
Public contact	Klinik und Poliklinik für Chirurgie, Universitätsklinikum Regensburg, +49 9419446801, hans.schlitt@ukr.de
Scientific contact	Klinik und Poliklinik für Chirurgie, Universitätsklinikum Regensburg, +49 9419446801, hans.schlitt@ukr.de

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	28 May 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 May 2015
Global end of trial reached?	Yes
Global end of trial date	28 May 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the trial is to investigate the influence of CNI-free-"bottom up" immunosuppression compared to CNI-containing "bottom-up" immunosuppression and 5-day Cyclosporine delay and their influence on renal function at 12 months measured by estimated GFR using the abbreviated MDRD formula

Protection of trial subjects:

see results

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 October 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 22
Worldwide total number of subjects	22
EEA total number of subjects	22

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)	19
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

see results

Period 1

Period 1 title	Overall Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

see results

Arms

Arm title	Standard with CMI

Arm description: -

Arm type	see results
Investigational medicinal product name	Ciclosporin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Parenteral use

Dosage and administration details:

Ciclosporin (CsA) Gabe ab Tag 5

Number of subjects in period 1[1]	Standard with CMI
Started	8
Completed	8

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Entgegen der initialen Planung konnten aufgrund einer geringeren Anzahl an Transplantation
im oben angegeben Zeitraum insgesamt nur 22 Patienten rekrutiert werden, wobei 8 Patienten in Arm 1 und jeweils 7 Patienten in Arm 2 und Arm 3 eingeschlossen wurden

Baseline characteristics

End points

End points reporting groups

Reporting group title	Standard with CMI

Reporting group description: -

Primary: Nierenfunktion nach 12 Monaten

End point title	Nierenfunktion nach 12 Monaten[1]

End point description:

End point type	Primary

End point timeframe:

after 12 months

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: go to Ergebnisbericht for results

End point values	Standard with CMI			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: q				
number (not applicable)	8			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: see results	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	4

Frequency threshold for reporting non-serious adverse events: 5 %

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: go to Ergebnisbericht for results

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 February 2011	Recent experiences in our department showed that longer treatment intervals and higher light doses Bmay improve therapeutic and cosmetic outcome. Visit 1 is now scheduled up to 4 weeks after the screening (last protocol version: visit 1was scheduled up to 14 days after the screening) • Visit 2 is now scheduled 6 weeks (± 4 weeks) after visit 1 (last protocol version: visit 2 was scheduled 4 weeks after visit 1) • Visit 3 is now scheduled 6 weeks (± 4 weeks) after visit 2 (last protocol version: visit 3 was scheduled 4 weeks after visit 2) • Visite 4 is now scheduled 10 weeks (± 4 weeks) after visit 3 (last protocol version: visit 4 was scheduled 4 weeks after visit 3)

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported