Clinical trial results:
Hepatitis C in renal transplant recipients – Safety and efficacy of a conversion of immunosuppression to high-dose cyclosporine A and its impact on HCV-replication, parameters of liver function and glucose tolerance. An open label trial.

Summary

EudraCT number	2011-002267-26
Trial protocol	AT
Global end of trial date	01 February 2017
Results information	
Result version number	v1 (current)
This version publication date	10 February 2022
First version publication date	10 February 2022

Trial information

Trial identification	
Sponsor protocol code	13071981
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Währinger Gürtel 18-20, Vienn, Austria, 1090
Public contact	Ammon Handisurya, Medizinische Universität Wien, 0043 1404004495, ammon.handisurya@meduniwien.ac.at
Scientific contact	Ammon Handisurya, Medizinische Universität Wien, 0043 1404004495, ammon.handisurya@meduniwien.ac.at

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	24 July 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 May 2013
Global end of trial reached?	Yes
Global end of trial date	01 February 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the impact of a conversion to a cyclosporine A-based immunosuppressive regimen on HCV-replication and parameters of liver function in renal transplant recipients

Protection of trial subjects:

frequent control visits

Background therapy:

n/a

Evidence for comparator:

n/a

Actual start date of recruitment	01 August 2011
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	Austria: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	12
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All HCV-positive RTRs who were admitted at the outpatient department of the Division of Nephrology and Dialysis, Department of Medicine III, Medical University of Vienna, between 01-July-2011 and 31-Aug 2012, were assessed for eligibility.

Pre-assignment

Screening details:

Inclusion criteria comprised written informed consent, prior renal transplantation, current treatment with TAC, HCV infection and age 18–70 years. Subjects with known CyA-intolerance or current renal replacement therapy and pregnant or breastfeeding women were excluded.

Period 1

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

Arms

Arm title	CyA Sandimmun capsules

Arm description:

to twice daily
oral CyA (Sandimmun capsules, Novartis GmBH)

Arm type	Active comparator
Investigational medicinal product name	CyA (Sandimmun capsules, Novaritis GmbH)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

twice daily

Number of subjects in period 1	CyA Sandimmun capsules
Started	12
Completed	10
Not completed	2
missing data at baseline	1
changes in confounding concomitant medication	1

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	12	12	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	12	12	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	2	2	
Male	10	10	

Subject analysis sets

Subject analysis set title	before conversion
Subject analysis set type	Full analysis

Subject analysis set description:

study participants, who entered the final analysis.
Of 12 subjects, who entered the study, one subject was excluded due to missing data at baseline and one subject was excluded due to changes in confounding concomitant medication

Subject analysis set title	after conversion
Subject analysis set type	Full analysis

Subject analysis set description:

study participants, who entered the final analysis.
Of 12 subjects, who entered the study, one subject was excluded due to missing data at baseline and one subject was excluded due to changes in confounding concomitant medication

Reporting group values	before conversion	after conversion	
Number of subjects	10	10	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	

Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	10	10	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	2	2	
Male	8	8	

End points

End points reporting groups

Reporting group title	CyA Sandimmun capsules
Reporting group description: to twice daily oral CyA (Sandimmun capsules, Novartis GmBH)	
Subject analysis set title	before conversion
Subject analysis set type	Full analysis
Subject analysis set description: study participants, who entered the final analysis. Of 12 subjects, who entered the study, one subject was excluded due to missing data at baseline and one subject was excluded due to changes in confounding concomitant medication	
Subject analysis set title	after conversion
Subject analysis set type	Full analysis
Subject analysis set description: study participants, who entered the final analysis. Of 12 subjects, who entered the study, one subject was excluded due to missing data at baseline and one subject was excluded due to changes in confounding concomitant medication	

Primary: difference in OGIS

End point title	difference in OGIS
End point description:	
End point type	Primary
End point timeframe: at baseline and after three months	

End point values	before conversion	after conversion		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	10		
Units: mL/min/m2				
median (inter-quartile range (Q1-Q3))	422.17 (370.82 to 441.92)	468.80 (414.27 to 488.57)		

Statistical analyses

Statistical analysis title	Primary
Statistical analysis description: Considering insulin sensitivity as the primary endpoint, a post-hoc analysis found that a sample size of 10 had 99% power to detect a difference in OGIS of 47 ml min-1m-2, with a standard deviation of 31 using a paired t-test with a 0.05 two-sided significance level	
Comparison groups	before conversion v after conversion

Number of subjects included in analysis	20
Analysis specification	Post-hoc
Analysis type	other
P-value	< 0.05
Method	SAS Enterprise Guide

Primary: HCV-PCR

End point title	HCV-PCR

End point description:

End point type	Primary

End point timeframe:

at baseline and after three months

End point values	before conversion	after conversion		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	10		
Units: copies/mL				
median (inter-quartile range (Q1-Q3))	546000 (351750 to 2965000)	2560000 (798000 to 3370000)		

Statistical analyses

Statistical analysis title	Primary

Statistical analysis description:

study participants, who entered the final analysis.
Of 12 subjects, who entered the study, one subject was excluded due to missing data at baseline and one subject was excluded due to changes in confounding concomitant medication

Comparison groups	before conversion v after conversion
Number of subjects included in analysis	20
Analysis specification	Post-hoc
Analysis type	other
P-value	< 0.285
Method	SAS Enterprise Guide

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

during control visits, at least once monthly

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Overall trial

Reporting group description:

Study population

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		

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: There was no non-serious adverse event

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported