Clinical trial results:
Differences in response to treatment with mycophenolic acid (MPA).

Summary

EudraCT number	2009-014997-16
Trial protocol	AT
Global end of trial date	03 June 2014

Results information

Result version number	v1 (current)
This version publication date	26 February 2021
First version publication date	26 February 2021

Trial information

Trial identification

Sponsor protocol code	MPASNP1

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	Waehringer Guertel 18-20, Vienna, Austria,
Public contact	Division of Nephrology and Dialysis, Medical University of Vienna, 0043 14040043890, guerkan.sengoelge@meduniwien.ac.at
Scientific contact	Division of Nephrology and Dialysis, Medical University of Vienna, 0043 14040043890, guerkan.sengoelge@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	Interim
Date of interim/final analysis	18 September 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 June 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Detection of functionally relevant SNPs in IMPDH 2 gene.

Protection of trial subjects:

Insurance for each study subject, exclusion of minors and persons not capable of written informed consent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 January 2010
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: 155
Worldwide total number of subjects	155
EEA total number of subjects	155

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)	102
From 65 to 84 years	53
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Adult kidney allograft recipients

Pre-assignment

Screening details:

Screening of all adult kidney allograft recipients on a consecutive Basis.
Exclusion ctiteria: Pregnancy, Age below 18 years.

Period 1

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

Arms

Arm title	Observation arm

Arm description: -

Arm type	Observation arm
Investigational medicinal product name	MPA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Standard dosage: 180mg-720mg bid

Number of subjects in period 1	Observation arm
Started	155
Completed	155

Baseline characteristics

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	155	155	
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)	102	102	
From 65-84 years	53	53	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	49	49	
Male	106	106	

Subject analysis sets

Subject analysis set title	Overall trial
Subject analysis set type	Per protocol

Subject analysis set description:

In this study, subjects with and without kidney transplant rejection were tested for the presence of rs11706052 SNP by genetic sequencing.

Reporting group values	Overall trial		
Number of subjects	155		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	102		
From 65-84 years	53		
85 years and over	0		

Gender categorical Units: Subjects			
Female	49		
Male	106		

End points

End points reporting groups

Reporting group title	Observation arm
Reporting group description: -	
Subject analysis set title	Overall trial
Subject analysis set type	Per protocol

Subject analysis set description:

In this study, subjects with and without kidney transplant rejection were tested for the presence of rs11706052 SNP by genetic sequencing.

Primary: IMPDH 2 single nucleotide polymorphisms

End point title	IMPDH 2 single nucleotide polymorphisms

End point description:

End point type	Primary

End point timeframe:

Within the study period beginning from the time of kidney transplantation

End point values	Observation arm	Overall trial		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	155	155		
Units: number of patients	155	155		

Statistical analyses

Statistical analysis title	logistic regression analysis
Comparison groups	Observation arm v Overall trial
Number of subjects included in analysis	310
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	< 0.05
Method	Regression, Logistic

Notes:

[1] - In this study, subjects with and without kidney transplant rejection were tested for the presence of rs11706052 SNP by genetic sequencing.

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 09.02.2010 - 03.06.2014	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	SNOMED CT
Dictionary version	2014

Reporting groups	
Reporting group title	Adverse Event

Reporting group description: -

Serious adverse events	Adverse Event		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 155 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Adverse Event		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 155 (9.03%)		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	14 / 155 (9.03%)		
occurrences (all)	25		

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