



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 criteria: 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