



Clinical trial results:

Tracleer - Therapie bei Patienten mit Downsyndrom und Eisenmengerreaktion: Verträglichkeit und hämodynamische Wirkungen. Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2005-005584-28 |
| Trial protocol | AT |
| Global end of trial date | 30 June 2006 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 13 December 2021 |
| First version publication date | 13 December 2021 |

Trial information

Trial identification

| | |
|-----------------------|---------------------|
| Sponsor protocol code | Version 1 4.11.2005 |
|-----------------------|---------------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| Sponsor organisation name | Medical University Innsbruck |
| Sponsor organisation address | Christoph-Probst-Platz 1, Innrain 52, Innsbruck, Austria, 6020 |
| Public contact | Univ.Prof. Dr. Ralf Geiger, Paediatrics III, Anichstrasse 35, 6020 Innsbruck, +43 (0)512-504-23510, ralf.geiger@tirol-kliniken.at |
| Scientific contact | Univ.Prof. Dr. Ralf Geiger, Paediatrics III, Anichstrasse 35, 6020 Innsbruck, +43 (0)512-504-23510, ralf.geiger@tirol-kliniken.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? | Yes |
| 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 | 30 June 2006 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|--------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 30 June 2006 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

1. Dokumentation der Effekte von Tracleer auf die systemische Sauerstoffsättigung bei Patienten mit Downsyndrom und Eisenmenger-Reaktion

Protection of trial subjects:

Trial has never been started.

Background therapy:

-

Evidence for comparator:

-

| | |
|-----------------------------------------------------------|---------------|
| Actual start date of recruitment | 13 March 2006 |
| 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: 99999 |
| Worldwide total number of subjects | 99999 |
| EEA total number of subjects | 99999 |

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) | 99999 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Trial has never been started. "99999" is a value for 0 participants.

Pre-assignment

Screening details:

Trial has never been started. "99999" is a value for 0 participants.

Period 1

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

Blinding implementation details:

Trial has never been started. "99999" is a value for 0 participants.

Arms

| | |
|-----------|----------|
| Arm title | Tracleer |
|-----------|----------|

Arm description:

Trial has never been started. "99999" is a value for 0 participants.

| | |
|----------------------------------------|---------------|
| Arm type | Experimental |
| Investigational medicinal product name | Tracleer |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Trial has never been started, administration details are not available.

| | |
|---------------------------------------|----------|
| Number of subjects in period 1 | Tracleer |
| Started | 99999 |
| Completed | 99999 |

Baseline characteristics

Reporting groups

| Reporting group title | Treatment |
|--------------------------------|-----------|
| Reporting group description: - | |

| Reporting group values | Treatment | Total | |
|-------------------------------------------------------|-----------|-------|--|
| Number of subjects | 99999 | 99999 | |
| 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) | 99999 | 99999 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 0 | 0 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 0 | | |
| standard deviation | ± 0 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 99999 | 99999 | |
| Male | 0 | 0 | |

End points

End points reporting groups

| | |
|------------------------------------------------------------------------------------------------------|----------|
| Reporting group title | Tracleer |
| Reporting group description: Trial has never been started. "99999" is a value for 0 participants. | |

Primary: Systemic oxygen saturation

| | |
|-----------------------------------------------------------------------------|-------------------------------------------|
| End point title | Systemic oxygen saturation ^[1] |
| End point description: Effects of Tracleer on systemic oxygen saturation | |
| End point type | Primary |
| End point timeframe: N/A | |

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: Trial has never been started. Therefore no statistical analysis has been done.

| End point values | Tracleer | | | |
|-----------------------------|----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 99999 ^[2] | | | |
| Units: N/A | | | | |
| number (not applicable) | 99999 | | | |

Notes:

[2] - Trial has never been started. "99999" is a value for 0 participants.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

13.03.2006- 30.06.2006

Adverse event reporting additional description:

Trial has never been started, therefore no AEs and SAEs have been reported.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|-------|
| Dictionary name | CTCAE |
|-----------------|-------|

| | |
|--------------------|-----|
| Dictionary version | 2.0 |
|--------------------|-----|

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | Tracleer |
|-----------------------|----------|

Reporting group description:

Trial has never been started. "99999" is a value for 0 participants.

| Serious adverse events | Tracleer | | |
|---------------------------------------------------|-------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 99999 (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 | Tracleer | | |
|-------------------------------------------------------|-------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 99999 (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: Trial has never been started, therefore no AEs and SAEs have been reported.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

| |
|----------------------------------------------------------------------|
| Trial has never been started. "99999" is a value for 0 participants. |
|----------------------------------------------------------------------|

Notes: