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
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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: