



Clinical trial results:

Effect of plasma volume expansion with hydroxy-ethyl-starch (HES) 130/0.4 or crystalloids on interstitial fluid accumulation and blood pressure in newborn infants with arterial hypotension

Summary

EudraCT number	2004-002096-16
Trial protocol	AT
Global end of trial date	31 December 2005

Results information

Result version number	v1 (current)
This version publication date	10 August 2022
First version publication date	10 August 2022

Trial information

Trial identification

Sponsor protocol code	01/04
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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	OA Dr. med. Salvador Navarro-Psihas, Bischof-Altmann-Str. 9, 94032 Passau, Kinderklinik Dritter Orden Passau, +49 0851 / 72 05 310, salvador.navarro-psihas@kinderklinik-passau.de
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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?	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	31 December 2005
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	31 December 2005
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

We investigate in newborns (e.g. term or preterm infants of less than 44 weeks postmenstrual age) with arterial hypotension, whether plasma volume expansion by HES 130/0.4 (Volumen) leads to less fluid loss into the interstitial space and increases the blood pressure more effectively and permanently than the administration of crystalloid solutions .

Protection of trial subjects:

N/A

Background therapy:

-

Evidence for comparator:

-

Actual start date of recruitment	24 May 2005
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)	99999
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

No patients were recruited for this trial. "99999" is a value for 0 participants.

Pre-assignment

Screening details:

N/A

Period 1

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

Arms

Arm title	Treatment
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Hydroxy-Ethyl-Starch 130/0,4
Investigational medicinal product code	
Other name	Voluven
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

N/A

Investigational medicinal product name	Isotonic electrolyte solution
Investigational medicinal product code	
Other name	Ringer Lactate
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

N/A

Number of subjects in period 1	Treatment
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title

Treatment

Reporting group description:

No patients were recruited for this trial. "99999" is a value for 0 participants.

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)	99999	99999	
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)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: days			
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	Treatment
Reporting group description: -	

Primary: Hydroxy-Ethyl-Starch 130/0,4/ Isotonic electrolyte solution

End point title	Hydroxy-Ethyl-Starch 130/0,4/ Isotonic electrolyte solution ^[1]
End point description:	

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: No patients were enrolled in this trial, therefore no statistical analysis was performed.

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	99999 ^[2]			
Units: N/A				
number (not applicable)	1			

Notes:

[2] - "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:

24.05.2005-31.12.2005

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	2.0
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Frequency threshold for reporting non-serious adverse events: 5 %

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: No patients were enrolled in this trial, therefore no AEs or SAEs were observed.

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.

No patients were enrolled in this trial. "99999" is a value for 0 participants.

Notes: