Clinical trial results:
Behandling ved intraventrikulær blødning:
Et pilotstudie af virkningen med tidlig intraventrikulær actilysebehandling.

Summary

EudraCT number	2008-008215-25
Trial protocol	DK
Global end of trial date	08 August 2011

Results information

Result version number	v1 (current)
This version publication date	25 October 2017
First version publication date	25 October 2017

Trial information

Trial identification

Sponsor protocol code	H-A-2008-109

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Walter Fischer
Sponsor organisation address	Blegdamsvej 9, Copenhagen, Denmark,
Public contact	Walter Fischer, Walter Fischer, w.fischer@telia.com
Scientific contact	Walter Fischer, Walter Fischer, 0045 35458230 , walter.fischer@regionh.dk

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	08 August 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 August 2011
Global end of trial reached?	Yes
Global end of trial date	08 August 2011
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The objective of the present trial is to show that Actilyse removes blood from the ventricles of the brain, more efficiently than NaCl.

Protection of trial subjects:

Patients with ongoing anticoagulant treatment presenting with an intracerebroventricular blood clot had their coagulation status normalised prior to Actilyse treatment of the blood clot in the brain.

Background therapy:

None

Evidence for comparator: -

Actual start date of recruitment	11 August 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	Denmark: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	4
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Date:2010-02-12
Period:2010-02-12 - 2011-08-11
Region:Copenhagen, Denmark

Pre-assignment

Screening details:

Screened subjects:12
Included subjects:12

Pre-assignment period milestones

Number of subjects started	12
Number of subjects completed	12

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Actilyse

Arm description:

Treatment with Actilyse, which brakes down the blood clot in the brain

Arm type	Experimental
Investigational medicinal product name	Actilyse
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intracerebroventricular use

Dosage and administration details:

4 mg (1 mg/ml) = 4 ml intracerebroventricularly

Arm title	Control

Arm description:

4 ml of NaCl 0.9%

Arm type	Placebo
Investigational medicinal product name	Sodium Chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intracerebroventricular use

Dosage and administration details:

4 ml NaCl was infused intracerebroventricularly

Number of subjects in period 1	Actilyse	Control
Started	8	4
Completed	8	4

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial
Reporting group description:	
Subjects 18-84 years of age with intracerebroventricular blood clots in the brain.	

Reporting group values	Overall trial	Total	
Number of subjects	12	12	
Age categorical			
Patients enrolled were over 18 years of age			
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)	4	4	
From 65-84 years	8	8	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	7	7	
Male	5	5	

Subject analysis sets	
Subject analysis set title	Actilyse
Subject analysis set type	Per protocol
Subject analysis set description:	
Experimental group	
Subject analysis set title	Control
Subject analysis set type	Per protocol
Subject analysis set description:	
NaCl	

Reporting group values	Actilyse	Control	
Number of subjects	8	4	
Age categorical			
Patients enrolled were over 18 years of age			
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)	3	1	
From 65-84 years	5	3	
85 years and over		0	
Gender categorical Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	Actilyse
Reporting group description:	
Treatment with Actilyse, which brakes down the blood clot in the brain	
Reporting group title	Control
Reporting group description:	
4 ml of NaCl 0.9%	
Subject analysis set title	Actilyse
Subject analysis set type	Per protocol
Subject analysis set description:	
Experimental group	
Subject analysis set title	Control
Subject analysis set type	Per protocol
Subject analysis set description:	
NaCl	

Primary: LeRoux Blood clot volume score

End point title	LeRoux Blood clot volume score[1]
End point description:	
The blood volume of the ventricles are scored accordingly: 4 = completely filled with blood 3 = more than half filled with blood 2 = less than half filled with blood 1 = traces of blood	
End point type	Primary
End point timeframe:	
2010-1011	

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: The trial had to be terminated due to the fact that a monitoring committee had not been assigned. By then too few individuals had been included in the trial in order to perform any meaningful statistical analysis.

End point values	Actilyse	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	4		
Units: 1				
number (not applicable)	25	39		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 2010-2011	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 1 %

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: There was one non-serious adverse event (CSF infection) but I cannot open the "box" for this category in the present data form:
Non-serious adverse events (lacks a +)
No non-serious adverse events have been specified.

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