Clinical trial results:
Volumekinetics for hyperoncotic albumin in burn patients as well as for healthy subjects.

Summary

EudraCT number	2016-000996-26
Trial protocol	SE
Global end of trial date	31 January 2019

Results information

Result version number	v1 (current)
This version publication date	15 February 2025
First version publication date	15 February 2025
Summary attachment (see zip file)	Summery VAB (Summery VAB.docx)

Trial information

Trial identification

Sponsor protocol code	VAB1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02352378
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Region Ostergotland
Sponsor organisation address	University Hospital, Linköping, Sweden, 58185
Public contact	Burn Unit, Region Ostergotland, +46 101031154, joachim.zdolsek@regionostergotland.se
Scientific contact	Burn Unit, Region Ostergotland, +46 101031154, joachim.zdolsek@regionostergotland.se

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	30 June 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 January 2019
Global end of trial reached?	Yes
Global end of trial date	31 January 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study if intravenously administered hyperoncotic albumin can attract fluid from the interstitium to the cirkulation in healthy individuals and in burn patients.

Protection of trial subjects:

Trial subjects were monitored with ECG and Saturation (oxygen) and intermittent (continous if they had an arterial line) blodpressure.
When registered in compure programs (Excel) the id of the trial subject was deindetified.

Background therapy:

Albumin solution is commonly used in treatment of hypovolemia or in during the deresusitation phase in the intensive care setting.

Evidence for comparator: -

Actual start date of recruitment	01 August 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Sweden: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	28
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Healthy subjects 15 and burn patients 15, who were able to give written and signed concent

Pre-assignment

Screening details:

Healthy for healthy subjects
Patients with a burnwound in need of advanced burn treatment

Pre-assignment period milestones

Number of subjects started	30
Number of subjects completed	30

Period 1

Period 1 title	Study period 5 hours (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Healthy volunteers

Arm description:

Healthy volunteers

Arm type	Active comparator
Investigational medicinal product name	Albumin 20%
Investigational medicinal product code	PR 1
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

3ml per kilo bodyweight of Albumin 20% which is 600mg albumin for every kilo body weight
(For a person of 70 kilo bodyweight this will be a mass of 42 g albumin)

Arm title	Burns

Arm description:

Burned patient in need of advanced burn care. Study performed 3 to 10 days postburn.

Arm type	Experimental
Investigational medicinal product name	Albumin 20%
Investigational medicinal product code	PR 1
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

3ml per kilo bodyweight of Albumin 20% which is 600mg albumin for every kilo body weight
(For a person of 70 kilo bodyweight this will be a mass of 42 g albumin)

Number of subjects in period 1	Healthy volunteers	Burns
Started	15	15
Completed	15	15

Baseline characteristics

Reporting groups	
Reporting group title	Healthy volunteers
Reporting group description:	
Healthy volunteers	
Reporting group title	Burns
Reporting group description:	
Burned patient in need of advanced burn care. Study performed 3 to 10 days postburn.	

Reporting group values	Healthy volunteers	Burns	Total
Number of subjects	15	15	30
Age categorical			
Health volunteers and burn patients			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	15	13	28
From 65-84 years	0	2	2
85 years and over	0	0	0
Age continuous			
Units: years			
median	31	45	
standard deviation	± 12	± 15	-
Gender categorical			
Units: Subjects			
Female	6	3	9
Male	9	12	21

End points

End points reporting groups	
Reporting group title	Healthy volunteers
Reporting group description: Healthy volunteers	
Reporting group title	Burns
Reporting group description: Burned patient in need of advanced burn care. Study performed 3 to 10 days postburn.	

Primary: Plasma volume expansion	
End point title	Plasma volume expansion
End point description:	
End point type	Primary
End point timeframe: 60 minutes after start of infusion, i.e. 30 minutes after end of infusion	

End point values	Healthy volunteers	Burns		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: L				
arithmetic mean (standard deviation)	0.43 (± 0.18)	0.59 (± 0.22)		

Statistical analyses

Statistical analysis title	Mann-Whitney U test
Comparison groups	Healthy volunteers v Burns
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Mann-Whitney U test
Parameter estimate	Mean difference (final values)
Variability estimate	Standard deviation

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 300 minutes	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups	
Reporting group title	Subcutaneous infusion

Reporting group description: -

Serious adverse events	Subcutaneous infusion		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (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	Subcutaneous infusion		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
Skin and subcutaneous tissue disorders			
subcutaneous infusion	Additional description: Subcutaneous infusion. Infusion was discontinued and the subject returned at a later occasion.		
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		

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

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/32366324