Clinical trial results:
Vasculopathic Injury and Plasma as Endothelial Rescue in septic shock (SHOCK) trial

Summary

EudraCT number	2017-000427-27
Trial protocol	DK
Global end of trial date	17 April 2019

Results information

Result version number	v1 (current)
This version publication date	09 February 2022
First version publication date	09 February 2022

Trial information

Trial identification

Sponsor protocol code	VIPER-SHOCK

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03092245
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet, Section for Transfusion Medicine, Capitol Region Blood Bank
Sponsor organisation address	Blegdamsvej 9, Copenhagen, Denmark, DK-2100
Public contact	Jakob Stensballe, Section for Transfusion Medicine, Capitol Region Blood Bank, 45 35458587, jakob.stensballe@regionh.dk
Scientific contact	Jakob Stensballe, Section for Transfusion Medicine, Capitol Region Blood Bank, +45 35458587, jakob.stensballe@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	03 November 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 April 2019
Global end of trial reached?	Yes
Global end of trial date	17 April 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficacy of OctaplasLG® administration as compared to crystalloids (standard of care) in patients with septic shock

Protection of trial subjects:

All patients are admitted to the ICU and therefore in a hospital setting.
Special safety markeres specially related to organfailure are observed during the study such as TACO and TRALI

Background therapy:

All patients receive normal standard of care treatment at the ICU

Evidence for comparator:

Comparator i standard of care

Actual start date of recruitment	18 April 2017
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: 55
Worldwide total number of subjects	55
EEA total number of subjects	55

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)	16
From 65 to 84 years	38

85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Patients were screened for inclusion upon admission to the ICU with septic shock

Pre-assignment

Screening details:

Screenings criteria were: 18 years old or above, admitted to the ICU at Bispebjerg Hospital, fulfilling the cirteria for septic shock (defined as need for vasopressor and lactate above 2 mmol/l), need for mechanical ventilation, need for naradrenalin at 0,1 mcg/kg/min or above

Period 1

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

Blinding implementation details:

Open label trail

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention arm

Arm description: -

Arm type	Experimental
Investigational medicinal product name	OctaplasLG
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Dosage according to trial algorithm

Arm title	Standard of care

Arm description:

The standard of care group will receive crystalloids as volumen support according to trail algorithm

Arm type	Active comparator
Investigational medicinal product name	Ringer acetate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

all types of crystalloids can be used. the most common type i ringer acetate.

Number of subjects in period 1	Intervention arm	Standard of care
Started	28	27
Completed	20	24
Not completed	8	3
Transferred to other hospital	1	-
Error in microscan	1	1
Died before 24 hours	-	2
Died	3	-
Protocol deviation	3	-

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	55	55	
Age categorical Units: Subjects			
Adults (18-64 years)	16	16	
From 65-84 years	38	38	
85 years and over	1	1	
Gender categorical			
Both male and female patients at 18 years old or above could be included			
Units: Subjects			
Female	25	25	
Male	30	30	

End points

End points reporting groups	
Reporting group title	Intervention arm
Reporting group description: -	
Reporting group title	Standard of care
Reporting group description:	
The standard of care group will receive crystalloids as volumen support according to trail algorithm	

Primary: Change in micorvascular perfusion	
End point title	Change in micorvascular perfusion
End point description:	
The data describe mean change/diffrence i microvascular perfusion from baseline to 24 hours between the 2 groups	
End point type	Primary
End point timeframe:	
From baseline to 24 hours	

End point values	Intervention arm	Standard of care		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28	27		
Units: mm/mm2				
log mean (standard error)				
PPV	-1.528 (± 1.101)	0 (± 0)		
PVD	-2.2931 (± 0.2479)	0 (± 0)		

Statistical analyses

Statistical analysis title	Primary endpoint
Comparison groups	Intervention arm v Standard of care
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	ANCOVA

Secondary: Mortality at 24h	
End point title	Mortality at 24h

End point description: Number of death at 24 hours	
End point type	Secondary
End point timeframe: mortality at 24 hours	

End point values	Intervention arm	Standard of care		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28[1]	27[2]		
Units: number				
Death	3	2		

Notes:

[1] - ITT analysis

[2] - ITT analysis

Statistical analyses

Statistical analysis title	ITT mortality at 24h
Comparison groups	Intervention arm v Standard of care
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.747
Method	Fisher exact

Secondary: Mortality at day 30	
End point title	Mortality at day 30
End point description: number of deaths at day 30	
End point type	Secondary
End point timeframe: Mortality at day 30	

End point values	Intervention arm	Standard of care		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28[3]	27[4]		
Units: number				
Death	12	7		

Notes:

[3] - ITT analysis

[4] - ITT analysis

Statistical analyses

Statistical analysis title	ITT mortality at dag 30
Comparison groups	Intervention arm v Standard of care
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.25
Method	Fisher exact

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Until day 30	
Adverse event reporting additional description:	
Only SAR and some SAE of special interests will be recorded at these patients are admitted to an ICU and therefore critical ill and will experience AE all the time without any benefit for safety issues. SAE/SAR are recorded based on the patients medical record.	
Assessment type	Systematic

Dictionary used	
Dictionary name	none
Dictionary version	0

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: Only SAR and some SAE are recorded for these patients as these are admitted to the ICU. NO SAE or SAR are 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

None reported