Clinical trial results:
Prospective, controled, randomized, double blind monocentric study evaluating the efficacy of the basic component of colloids (corn versus potato) on perioperative blood losses in elective cardiac surgery.

Summary

EudraCT number	2011-005920-16
Trial protocol	BE
Global end of trial date	13 October 2015

Results information

Result version number	v1 (current)
This version publication date	29 July 2021
First version publication date	29 July 2021

Trial information

Trial identification

Sponsor protocol code	CHUB-930105

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	CHU Brugmann
Sponsor organisation address	4 Place A Van Gehuchten , Brussels, Belgium, 1020
Public contact	Anesthesiology Department, CHU Brugmann, 32 024773996, Philippe.VANDERLINDEN@chu-brugmann.be
Scientific contact	Anesthesiology Department, CHU Brugmann, 32 024773996, Philippe.VANDERLINDEN@chu-brugmann.be

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	13 October 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 September 2014
Global end of trial reached?	Yes
Global end of trial date	13 October 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Security of hydroxyethyl starches

Protection of trial subjects:

Procedures according to the standard of care.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 March 2012
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	Belgium: 118
Worldwide total number of subjects	118
EEA total number of subjects	118

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)	54
From 65 to 84 years	58
85 years and over	6

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

227 patients were assessed for eligibility. 118 patients were randomized.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Maize-HES

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Volulyte 6%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Maximum dose of 50ml/kg of a 6% solution of Volulyte

Arm title	Potato-HES

Arm description: -

Arm type	Experimental
Investigational medicinal product name	PlasmaVolume Redibag 6%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Injection

Dosage and administration details:

Maximum dose of 50ml/kg of the 6% Plasma Redibag solution.

Number of subjects in period 1	Maize-HES	Potato-HES
Started	59	59
Completed	59	59

Baseline characteristics

Reporting groups	
Reporting group title	Maize-HES
Reporting group description: -	
Reporting group title	Potato-HES

Reporting group description: -

Reporting group values	Maize-HES	Potato-HES	Total
Number of subjects	59	59	118
Age categorical 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)	32	22	54
From 65-84 years	25	33	58
85 years and over	2	4	6
Gender categorical Units: Subjects			
Female	16	19	35
Male	43	40	83

End points

End points reporting groups	
Reporting group title	Maize-HES
Reporting group description: -	
Reporting group title	Potato-HES
Reporting group description: -	

Primary: Blood loss	
End point title	Blood loss
End point description:	
End point type	Primary
End point timeframe: Postoperative day 2	

End point values	Maize-HES	Potato-HES		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	59		
Units: ml	504	530		

Statistical analyses

Statistical analysis title	Mann-Whitney U test
Comparison groups	Maize-HES v Potato-HES
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Overall trial	
Assessment type	Systematic

Dictionary used	
Dictionary name	Clinical Practice
Dictionary version	N/A

Reporting groups	
Reporting group title	Maize-HES
Reporting group description: -	
Reporting group title	Potato-HES
Reporting group description: -	

Serious adverse events	Maize-HES	Potato-HES	
Total subjects affected by serious adverse events			
subjects affected / exposed	39 / 59 (66.10%)	34 / 59 (57.63%)	
number of deaths (all causes)	4	4	
number of deaths resulting from adverse events			
Investigations			
Death	Additional description: Long-term follow-up, unknown causes		
subjects affected / exposed	2 / 59 (3.39%)	2 / 59 (3.39%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 2	
Surgical and medical procedures			
Aortic rupture			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac disorders			
Cardiogenic shock			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrial fibrillation			

subjects affected / exposed	14 / 59 (23.73%)	17 / 59 (28.81%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Stroke			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Postoperative delirium			
subjects affected / exposed	7 / 59 (11.86%)	2 / 59 (3.39%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Redo surgery for hemostasis			
subjects affected / exposed	1 / 59 (1.69%)	3 / 59 (5.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Respiratory insufficiency (death)			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory insufficiency			
subjects affected / exposed	17 / 59 (28.81%)	12 / 59 (20.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal replacement therapy			
subjects affected / exposed	2 / 59 (3.39%)	1 / 59 (1.69%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Maize-HES	Potato-HES	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 59 (13.56%)	8 / 59 (13.56%)	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	8 / 59 (13.56%)	8 / 59 (13.56%)	
occurrences (all)	1	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 May 2015	Protocol V1.2 - 07/05/2015 Addition of a quality of life questionnaire (MacNew score) during a telephone contact made 1 year after their surgery. Extension of the total duration of the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported