



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 | Subject, Investigator, Assessor |

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