Comparison of Volulyte® versus Tetraspan® in patients undergoing cardiopulmonary bypass.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21191

Source
NTR

Brief title
N/A

Health condition

cardiopulmonary bypass, balanced hydroxyethyl starch, cardiac surgery

Sponsors and support

Primary sponsor: Universitair Ziekenhuis Brussel
Laarbeeklaan 101
1090 Jette Brussels
Source(s) of monetary or material Support: Universitair Ziekenhuis Brussel
Laarbeeklaan 101
1090 Jette Brussels

Intervention

Outcome measures

Primary outcome

1. Coagulation status;

2. Colloid osmotic pressure;

3. Acid/base balance and ion balance.

Secondary outcome

1. Blood loss;

2. Morbidity.

Study description

Background summary

The study is designed to elucidate the differences in coagulation profile, acid-base status, ionogram, colloid oncotic pressure and organ function in patients undergoing cardiopulmonary bypass during cardiac valvular surgery.

Study objective

Does the use of two different balanced hydroxyethyl starch solutions, influence the coagulation profile, acid-base status, ionogram, colloid oncotic pressure and organ function in patients undergoing cardiopulmonary bypass.

Study design

After induction of anesthesia, after 15 min. on cardiopulmonary bypass, after cardiopulmonary bypass, first postoperative day.

Intervention

Administration of Tetraspan versus Volulyte in cardiopulmonary bypass priming and as resuscitation fluid during valvular cardiac surgery.

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients undergoing valvular cardiac surgery with cardiopulmonary bypass.

Exclusion criteria

Patients with preoperative renal failure, redo or urgent operations, IABP.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-12-2011
Enrollment:	60

Type:	Anticipated

Ethics review

Positive opinion

Date:	10-11-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2989
NTR-old	NTR3137
Other	MEC UZ Brussel : 2011/189
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A