

Can a novel perfusion monitor help us defining optimal flow for patients on cardiopulmonary bypass.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28731

Source

NTR

Brief title

N/A

Health condition

Cardiopulmonary bypass, perfusion monitor, cardiovascular patients, adequate oxygen delivery, hypo-perfusion, hyper perfusion, postoperative complications, individual circulatory treatment.

Sponsors and support

Primary sponsor: Universitair Ziekenhuis Brussel

Laarbeeklaan 101

1090 Jette

Source(s) of monetary or material Support: Universitair Ziekenhuis Brussel

Laarbeeklaan 101

1090 Jette

Intervention

Outcome measures

Primary outcome

Which oxygen flow gives hyperlactatemia?

Secondary outcome

Evaluation of kidney function.

Study description

Background summary

Adequate oxygen delivery (D02) to the organs and tissues of the cardiovascular patient is the primary principle of putting patients on cardiopulmonary bypass (CPB). The golden standard for calculation of flow is 2,4 L/min/m² body surface area (BSA). Blood flow during CPB is standardized worldwide; i.e. 2,2-2,5 LPM/m². There is an increasing tendency towards a more individual circulatory treatment. In fact, individualized goal-directed therapy has been shown to reduce postoperative complications and mortality in high-risk surgery.

Hypo-perfusion (defined as the inadequate delivery of oxygen) and the resulting Hyperlactatemia are well described and quantified, as well as their postoperative consequences. The effects of hyper-perfusion are far less investigated.

A new perfusion monitor is developed to continuously monitor, in real-time and online, the different determinants of oxygen delivery and oxygen consumption of the patient.

Study objective

Evaluation of the golden standard in perfusion by using a perfusion monitor to evaluate adequate oxygen delivery.

Study design

- 1) Blood gas before cardiopulmonary bypass(CPB), after 10', 30', 60', 90', 120' and post CPB.
- 2) Postoperative we will also look at the highest lactate level during hospital stay.

Intervention

Arterial and venous connector for inline measurement. Regular blood gas analysis. Blood flow sensor measurement.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients scheduled for cardiac surgery.
- Normothermic cases and maximum duration less than 2 hours.

Exclusion criteria

- Complicated cases
- CPB duration over 2 hours
- renal insufficiency
- emergency
- reanimation
- salvage and existing inflammatory conditions.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	17-02-2014
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion	
Date:	23-04-2014
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

NTR-new

NTR-old

Other

ID

NL4399

NTR4596

MEC UZ Brussel : 2014/017

Study results

Summary results

N/A