Evaluation of cerebral circulation and metabolic properties in patients undergoing normothermic cardiopulmonary bypass with acute normovolemic hemodilution.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	-

Summary

ID

NL-OMON28354

Source
NTR

Brief title
Hemodilution and cerebral autoregulation.

Health condition

cardiopulmonary bypass, hemodiltion, cerebral autoregulation, micro embolic signals.

Sponsors and support

Primary sponsor: Jos Maessen, MD, PhD
Maastricht University Medical Center, Dept. CTC
Phone: +31-43-3877070
Source(s) of monetary or material Support: Jos Maessen, MD, PhD
Maastricht University Medical Center, Dept. CTC
Phone: +31-43-3877070

Intervention

Outcome measures

Primary outcome

To evaluate the effects of normovolemic hemodilution levels during CPB on the dynamic cerebral autoregulation and cerebrovascular reactivity.

Secondary outcome

1. To evaluate the dynamic cerebral autoregulation with transcranial Doppler velocity and near infrared spectroscopy at different PaCO2 levels during normothermic CPB;

2. To evaluate the relation between PaCO2 values and the amount of micro emboli signals during CPB.

Study description

Background summary

Rationale:
The objective of this clinical study is to endorse the hypothesis that acute normovolemic hemodilution during coronary artery bypass surgery involving normothermic cardiopulmonary bypass (CPB) may lead to dysfunction of cerebral autoregulation and therefore contribute to neurological morbidity after cardiac surgery.

Objectives:

Primary objective is to evaluate the effects of normovolemic hemodilution levels during CPB on the dynamic cerebral autoregulation (dCA) and cerebrovascular reactivity (CVR).

Secondary objective is to evaluate dCA with transcranial Doppler (TCD) velocity and near infrared spectroscopy (NIRS) at different arterial carbon dioxide tension (PaCO2) levels during normothermic CPB.

Third objective is to evaluate the relation between PaCO2 values and the amount of micro embolic signals (MES) during CPB.

Study design:
A prospective randomized observational clinical trial.

Study population:
Forty adult male patients scheduled for elective coronary artery bypass grafting (CABG) surgery will be randomly divided in two groups. CPB will be conducted using either a standard minimized extracorporeal circuit (MEC) or a conventional extracorporeal circuit (CEC).

Intervention (if applicable):

Not applicable.

Main study parameters/endpoints:

Primary endpoint: Difference of dCA and CVR measured by TCD and NIRS.

Secondary endpoints: PaCO2 levels and amount of MES during CPB.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: No additional risk than for those patients undergoing CABG surgery that are not involve in the study. Differences in the two groups of extracorporeal systems regarding primary and secondary objective are to be investigated. Both devices have been successfully used clinically for years, and have been established as standard devices to take over heart and lung function during heart surgery.

Possible benefits:
Optimization of the CPB system and conduct in order to reduce CPB-related neurological morbidity after cardiac surgery.

Study objective

Acute normovolemic hemodilution during coronary artery bypass surgery involving normothermic cardiopulmonary bypass (CPB) leads to dysfunction of cerebral autoregulation and therefore contributes to neurological morbidity after cardiac surgery.

Study design

Only peroperative measurement of standard recorded data.

Intervention

N/A

Contacts

Public
Werner Mess
Maastricht University Medical Center,
Dept. KNF
Maastricht
The Netherlands
+31-(0)43-3875268
Scientific
Werner Mess
Maastricht University Medical Center,
Dept. KNF
Maastricht
The Netherlands
+31-(0)43-3875268

Eligibility criteria

Inclusion criteria

1. Elective adult candidates for CABG surgery using CPB;

2. Male gender;

3. Age: 50 -70 years old;

4. Presence of a trans-temporal bone window;

5. Informed written consent obtained by the patient.

Exclusion criteria

1. Patients suffering from neurological disorders (e.g. cerebrovascular accident);

2. Patients suffering from renal diseases (e.g. renal failure, defined as laboratory tests indicating values of 2 or more times the normal values [urea >= 50 U/L, kreatinine >= 170 micromol/L]);

3. Patients suffering from liver diseases, defined as laboratory tests indicating values of 2 or more times the normal values (ASAT >= 50 U/L, ALAT >= 60 U/L, LD >= 600 U/L and gamma-GT >= 90 U/L);

4. Patients suffering from severe pulmonary disorders (e.g. chronic obstructive pulmonary disease, emphysema);

5. Insulin / non insulin dependent diabetics;

6. Hypothermia during CPB;

7. Severe atherosclerosis of the carotid or the middle cerebral artery;

8. Participation in an investigational drug trial within the preceding 30 days.

Study design

Design

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2009
Enrollment:	40
Type:	Anticipated

Ethics review

Not applicable

Application type: Not applicable

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	NL1626
NTR-old	NTR1723
CCMO	NL27129
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A