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

Gepubliceerd: 12-03-2009 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON28354

Bron
NTR

Verkorte titel
Hemodilution and cerebral autoregulation.

Aandoening

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

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Only peroperative measurement of standard recorded data.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2009
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A