Helium and organ protection during bypass surgery

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Recent experimental and clinical data showed that the noble gas helium protects against myocardial reperfusion injury in rabbits in vivo and induces late preconditioning in rat hearts. It has also been demonstrated that another noble gas, xenon, can…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25552

Bron
NTR

Verkorte titel
HIPP-CABG

Aandoening

The aim of this clinical study is to investigate whether the non-anaesthetic noble gas helium induces preconditioning (PreC) and postconditioning (PostC) in patients undergoing coronary artery bypass graft (CABG) surgery.

Ondersteuning

Primaire sponsor: Academic Medical Centre Amsterdam
Meibergdreef 9
1100 DD Amsterdam
Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study parameters are detection of signalling pathway molecules involved in anaesthetic preconditioning (PKC-e, p38MAPK, ERK and HSP27). This will be done by molecular analysis of myocardial tissue samples in our laboratory.

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of this clinical study is to investigate whether the non-anaesthetic noble gas helium induces preconditioning (PreC) and postconditioning (PostC) in patients undergoing coronary artery bypass graft (CABG) surgery.
Primary endpoinst are detection of signalling pathway molecules (PKC-e, p38MAPK, ERK and HSP27) and secondary parameters include estimation of myocardial damage by measurement of cardiac enzymes.

Doel van het onderzoek

Recent experimental and clinical data showed that the noble gas helium protects against myocardial reperfusion injury in rabbits in vivo and induces late preconditioning in rat hearts. It has also been demonstrated that another noble gas, xenon, can protect from myocardial damage by postconditioning. Supported by this evidence we hypothesize that helium induces pre- and postconditioning in humans.

Onderzoeksopzet

Tissue samples for investigation of primary outcome will be taken during surgery, first and second sample will be taken during installation of cardiopulmonary bypass, third sample will be taken after weaning of cardiopulmonary bypass, when aorta cross clamp is taken off.

Bood samples for investigations of secondary outcomes will be taken at baseline (before surgery),4,12,24 and 48 hours after surgery.

Hemodynamic parameters will be obtained during surgery.

Onderzoeksproduct en/of interventie

First group of patients will receive 3 * 5 minutes of Helium just before aortic cross clamping (preconditioning, PreC,)

second group will receive helium 3*5 min just before release of the aortic cross clamp (Postconditioning, PostC,)

Third group will receive both regimens (pre and postconditioning, PrePostC,).

Fourth group of patients will serve as untreated controls (CON,)

Fifth group will serve as positive controls, and receive preconditioning with sevoflurane (3 * 5min) before aortic cross clamping (anaesthetic preconditioning, APC,)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age > 18 Years

2. Patients who have to undergo elective cardiac surgery (CABG without valve surgery)

3. Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years

2.Emergency operations

3. Pregnancy

4. Severe COPD

5. Absent informed consent

6. SaO2 < 90% at room temperature

7. Presumed non cooperatives

8. Legal incapacity

9. Diabetes Mellitus

10. Renal failure

11. Comined procedures

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2008
Aantal proefpersonen:	125
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-03-2008
Soort:	Eerste indiening

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	NL1181
NTR-old	NTR1226
Ander register	MEC : 08/050
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A