Validation of Strain and Strain Rate: a pilot study comparing transthoracic and transoesophageal echocardiography in patients undergoing coronary artery bypass grafting

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The primary endpoint of this study is to assess if myocardial strain and strain rate -measured with tissue Doppler and 2D speckle tracking- determined with TOE is comparable with cardiac strain and strain rate determined with TTE. Secondary...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26891

Bron
NTR

Aandoening

Patients referred for elective and in-house off pump coronary artery bypass (OPCAB)

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: NA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main endpoint of this study is to compare values of strain and strain rate measured with TOE and TTE.

Toelichting onderzoek

Achtergrond van het onderzoek

This is an observational prospective pilot study comparing myocardial strain values obtained with both TTE and TOE, involving patients undergoing off pump CABG (OPCAB).

Forty patients undergoing OPCAB will be included in this study. Beside standard clinical practice a transthoracic echocardiography will be performed three times perioperatively, i.e. before induction of anesthesia, before start of surgery, at the end of surgery. TTE data will be compared with TOE data to assess validity of the latter. Near infrared spectroscopy electrodes will be applied on the thorax of the patient, above the heart, outside the surgical field. Data of regional tissue oxygenation will be compared with echocardiographic data. Patients undergoing this study will not incur any extra risk, beside those from the operation itself

Doel van het onderzoek

The primary endpoint of this study is to assess if myocardial strain and strain rate -measured with tissue Doppler and 2D speckle tracking- determined with TOE is comparable with cardiac strain and strain rate determined with TTE.

Secondary endpoint is to validate echocardiographic systolic and diastolic parameters comparing values obtained with TTE with those obtained with TOE.

Onderzoeksopzet

Pre operative

Perioperative

Post operative

Onderzoeksproduct en/of interventie

There will be no medical intervention based on the data obtained with the study.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. patients older than 18 years

2. patients who can give informed consent

3. ejection fraction (EF) > 50%

4. patients referred for elective and in-house OPCAB

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. patients who are unable to give consent

2. patients < 18 years

3. patients who are already part of another randomized study

4. emergency OPCAB

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2014
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-09-2014
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	NL4659
NTR-old	NTR4802
Ander register	Strain 001 : METc 2013/404

Resultaten