Antispasmodic agents for radial artery conduit.

Gepubliceerd: 19-04-2013 Laatst bijgewerkt: 18-08-2022

Our hypothesis is that using nicardipine instead of verapamil in the vasodilation solution would increase the free flow.

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

Samenvatting

ID

NL-OMON23784

Bron
Nationaal Trial Register

Verkorte titel
Antispasm Radial

Aandoening

Treatment radial conduits in coronary artery bypass grafting

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: No funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Comparison between verapamil and nicardipine in preventing spasm and increasing direct free flow through the radial artery conduit.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

The use of local application of vasodilators such as calcium channel blockers and/or nitroglycerines leads to possible improvement of the blood flow via the radial artery conduit by avoiding perioperative spasm in comparison with the local application of saline solution.

Objective:

The main objective of the study is to investigate if the local application of vasodilators would improve the immediate flow through the prepared radial artery conduit.

Study design:

A prospective randomized non-blind mono-centre study.

Study population:

Patients who are scheduled for undergoing coronary artery bypass surgery with the use of the radial artery with or without other conduits.

Intervention:

After harvesting the radial artery and before performing the anastomoses, topical application of two different vasodilator solutions will be performed. One solution is being used in the standard practice of our department and contains 10 mg verapamil. In the other solution, verapamil is replaced by nicardipine (10 mg).

Main study parameters/endpoints:

The main endpoint of the study is the mean amount of free flow through the radial artery conduit. This is measured directly after harvesting the radial artery by allowing a free flow of

both solution through the conduit into an empty bowl. The mean amount of the solution (in ml) collected in one minute is calculated. This is considered as the mean free flow (ml/min) through the conduit.
Nature and extent of the burden and risks associated with participation: No risk is expected for patients who participate in this study. A possible benefit for the patients is the better antispastic action of nicardipine and therefore less incidence of perioperative ischemia.

Doel van het onderzoek

Our hypothesis is that using nicardipine instead of verapamil in the vasodilation solution would increase the free flow.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

This is a prospective randomized non-blinded study containing two groups of patients. In one group, the radial artery will be treated topically with the solution used in our daily practice which contains verapamil. In the other group, the same solution is used after replacing verapamil with nicardipine. Topical application of either solutions takes place only after harvesting the radial artery and before performing the anastomoses. After measuring the flow manually, the surgeon may use the radial artery conduit in his own manner for performing the anastomoses.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients undergoing isolated or combined CABG whereby the radial artery is used as a conduit with or without the use of other conduits.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Emergency Operation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2013
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	NL3793
NTR-old	NTR3966
Ander register	: HIO2013
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A