A Study To Evaluate The Safety And Feasibility Of Pressure-controlled Intermittent Coronary Sinus Occlusion (PICSO) In Patients With Coronary Artery Disease Undergoing Native Vessel Intervention

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The purpose of the study is to determine whether PICSO is safe and feasible using a femoral approach, and in what amount of cases PICSO is effective to increase collateral flow index (CFI).

Ethical review	-
Status	Pending
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON34428

Source
ToetsingOnline

Brief title
Safety And Feasibility Of PICSO

Condition

- Coronary artery disorders

Synonym
Coronary Artery Disease, Coronary Atherosclerosis

Research involving

Human

Sponsors and support

Primary sponsor: Miracor medical systems
Source(s) of monetary or material Support: Bedrijf: Miracor Medical Systems

Intervention

Keyword: CFpI, Collateral flow index, PICSO, Pressure-controlled intermittent coronary sinus occlusion

Outcome measures

Primary outcome

1. Duration from successful femoral vein cannulation untill successful

placement of PICSO Impulse catheter into the Coronary Sinus.

2. Relative increase in collateral flow pressure index (CFpI) during LAD

occlusion with and without PICSO.

Secondary outcome

1. Number of patients reaching collateral flow pressure index (CFpI) higher

than 30% during PICSO.

2. Quantitative evaluation of pre-condition effect on relative increase of CFpI.

3. The change of ST segment as recorded at Intra coronary ECG measures during

balloon inflation

Study description

Background summary

Good collateral flow in case of obstructive coronary artery disease and acute myocardial infarction has beneficial effects on morbidity and mortality [73, 74, 75]. Pressure controlled Intermittent Coronary Sinus Occlusion (PICSO) carries a promise of improving myocardial flow, decreasing microvascular

obstruction and decreasing the rate of peri-procedural and acute myocardial infarction without the increased risk of bleeding such as is encountered with gp2b3a inhibitors. We expect that PICSO is able to reduce infarct size in patients with acute myocardial infarction and will thus will be able to help us preserve cardiac function in case of infarction.

Study objective

The purpose of the study is to determine whether PICSO is safe and feasible using a femoral approach, and in what amount of cases PICSO is effective to increase collateral flow index (CFI).

Study design

This study is a non-randomized single center pilot study in which patients will act as their own controls in a cross-over design.

Intervention

Patients will be treated with PICSO. This treatment exists of PICSO catheter placement in the coronary sinus through a femoral vein approach by using a 12F steerable guiding catheter. During two short experimental balloon occlusions of maximum 3 minutes (or less when chest pain occurs), CFpI of the LAD artery will be measured with and without PICSO. During the following PCI-procedure, PICSO-treatment wil be performed continuously.

Study burden and risks

In essence, the possible complications are the same as during a normal elective PCI. Possible risks inherited by the use of the PICSO-catheter are:
Bleeding due to puncture of the femoral vein, chest complaints during occlusion of the coronary artery (in which case the occlusion will be stopped immediately), chronic occlusion or injury of the coronary sinus and pulmonary embolism.

The burden associated with participation in this study consists of 30 minutes of anamnesis, physical examination and ECG during first hospital admission and an elongation of the PCI-procedure of 30 minutes for research purposes. Also, 30 days after the procedure, a consult will take place by telephone for MACE-follow up which will take about 15 minutes

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Subjects at least 18 years of Age
- Stable patient
- Left Anterior Descending (LAD) Stenosis as assessed by angiography
- Able to understand content of and willing to provide written informed consent

Exclusion criteria

- Active and/or treated malignancies within 12 months prior to first Visit
- Anatomical Complications (e.g. The system is not able to effectively occlude the coronary sinus)
- Presence of significant collateral flow supplying the target vessel (Rentrop 2,3)
- Any significant systemic illness or medical condition that could lead to difficulty complying with the protocol; or any concurrent condition(s) which, in the investigator's opinion, would prohibit the subject from completing the study, or in which case the study would not be in the best interest of the subject.

- Bleeding or perforation during PCI, pericardial effusion and/or hematoma
- Cardiac arrest or arrythmia requiring chest compressions or cardiopulmonary resuscitation
- Cardiogenic shock (Cardiac index <1.8 L/min/m² or assessed by the investigator), pulmonary edema (Killip Class >2), or hemodynamic instability as assessed by the investigator at the time of cardiac catheterization.
- Clinically significant renal disturbance (sMDRD calculated GFR *30mL/min/1,73m²)
- Coronary Sinus electrode in place
- Acute ST elevation myocardial infarction
- Previous Q-wave myocardial infarction within 72 hours prior to screening
- Ejection Fraction <20%
- History of stroke, any sequelea of a transient ischemic attack (TIA) or reversible ischemic neurological defect (RIND) within 6 months prior to screening
- left bundle branch block
- mitral regurgitation (MR) > grade I
- mitral stenosis
- Patient not currently in sinus rythm
- patients on cardiac resynchronization therapy (CRT) or scheduled for CRT implantation
- Patients with previous CABG or planned chronic total occlusion revascularization
- Pregnancy or active breast-feeding. Urine pregnancy tests will be performed on all women who are not post-menopausal for at least 1 year.
- registration in another interventional study
- severe anemia at baseline (hemoglobin <10 g/dl or <6.2 mmol/l)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-07-2010
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Pressure-controlled Intermittend Coronary Sinus Occlusion Impulse Catheter
Registration:	No

Ethics review

Not available

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
CCMO	NL32821.018.10