Reduction in contrast volume and radiation with Magnetic Navigation: a Prospective Randomised Trial

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To show a reduction of contrast use and other procedural features such as radiation exposure, time to cross the culprit lesion with the wire and procedural time with an equivalent or better procedural success and complication rate.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON36899

Source
ToetsingOnline

Brief title
Contrast use and radiation reduction with magnetic navigation

Condition

- Coronary artery disorders

Synonym
angioplasty, percutaneous coronary intervention

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Elective percuteneous coronary intervention

Outcome measures

Primary outcome

The primary endpoint is the total contrast used.

Secondary outcome

Secondary endpoints will be

1. the contrast needed to cross the lesion,

2. the time needed to cross the lesion,

3. the total procedural time,

4. the total irradiation,

5. angiographic success rates, and

6. complications.

Study description

Background summary

Magnetic steering of an angioplasty wire is a new, method to steer an wire across a lesion as a part of a percutaneous coronary intervention. This is more precise and may therefore reduce the patient contrast use, radiation exposure and procedure time.

Features that may help reduce procedural features.
1. More precise steering of the wire with a system that has the 3 dimensional vectors to orientate the wire in the coronary artery. This may reduce the contrast usage and time needed to cross the lesion.
2. The ability to produce a 3D reconstruction from diagnostic angiography films and therefore reduce a). the need for giving contrast to visualize the vessel and b). the time taken for the initial preparation.
3. The ability of the system to place a white-line overlay directly on the fluoroscopy screen that orientates automatically with the x-ray view being

taken, that acts as a map to show the wire position, and particularly deviations from the correct direction.

The registry of magnetic procedures performed at the OLVG compared to conventional procedures in the same time period suggests a decrease in the contrast used without strict adherence to the 3 features described above.

Study objective

To show a reduction of contrast use and other procedural features such as radiation exposure, time to cross the culprit lesion with the wire and procedural time with an equivalent or better procedural success and complication rate.

Study design

This is a prospective, open study with patients randomised in a 1:1 ratio to use of conventional (manual) manipulation of a standard wire versus the use of a magnetically navigable wire. The procedures will otherwise follow standard methods of percutaneous coronary intervention.

Intervention

Magnetic navigation versus conventional procedure during percutaneous coronary intervention.

Study burden and risks

Participation in the trial will not give any extra risk to the patient. The expected contrast reduction and reduction in procedural times are associated with a lower complication rates.

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

§ Age>18 years
§ Elective presentation for PCI
§ Diagnostic coronary angiography films suitable for 3D reconstruction

Exclusion criteria

Acute coronary syndromes (unstable angina, MI) and chronic total occlusions

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2010
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	01-04-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT01276808
CCMO	NL17838.100.10