Comparison of regadenoson (rapiscan) and central intravenous adenosine for measurement of fractional flow reserve

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Comparison of adenosine infusion and bolus injection of regadenoson for induction of maximum coronary hyperemia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON37223

Source
ToetsingOnline

Brief title
Regadenoson and adenosine

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
Induction of maximum coronary hyperemia

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Het betreft een investigators driven studie die geinitieerd is door de afdeling cardiologie van het Catharina Ziekenhuis;welke afdeling ook zorgt voorde financiering van de studie.

Intervention

Keyword: Adenosine, Coronary hyperemia, Fractional Flow Reserve, Regadenoson

Outcome measures

Primary outcome

Degree of coronary hyperemia and duration of hyperemic plateau phase.

Secondary outcome

Not applicable.

Study description

Background summary

Intravenous adenosine infusion by a central venous access, is the gold standard for induction of maximum coronary hyperemia and assessment of Fractional Flow Reserve (FFR). The present study aims to investigate if a single bolus of regadenoson, administered in a central or peripheral vein, is equivalent to adenosine. If so, measurement of FFR is considerably simplified.

Study objective

Comparison of adenosine infusion and bolus injection of regadenoson for induction of maximum coronary hyperemia.

Study design

In patients admitted for FFR measurement, adenosine and regadenoson will be compared.

Study burden and risks

Prolongation of the procedure with 20 minutes. Everything else is completely equal to regular procedure.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

See protocol.;Among others:;Age 18-80 years;Scheduled for invasive measurement of FFR

Exclusion criteria

See protocol.;Among others:;Severe aortic valve stenosis;Severe COPD

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-01-2013
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Regadenoson (Rapidscan®)
Generic name:	Regadenoson (Rapidscan®)
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	10-12-2012
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
EudraCT	EUCTR2012-004582-40-NL
CCMO	NL42049.060.12