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Increase of adenosine doses in fractional flow reserve

Submission date
13/12/2016

Recruitment status
No longer recruiting

Registration date
15/12/2016

Overall study status
Completed

Last Edited
27/11/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Fractional flow reserve (FFR) is a method to measure blood flow that is used to assess stenosis (narrowing) of the coronary arteries (the blood vessels that supply the heart). In order for FFR to work properly, the blood flow in the coronary artery must be maximized, which is called hyperemia. This is achieved using a drug called adenosine. Different doses of adenosine are used in clinical practice, but an extensive comparison between the standard dose and a high dose has not previously been performed. The aim of this study is to assess the effects of an increased dose of adenosine in FFR and to look at its hemodynamic (blood flow) effects and patient discomfort.

Who can participate?
Patients aged 18 and over with stenosis undergoing coronary angiography (heart x-ray) and FFR

What does the study involve?
After coronary angiography, a guide wire is advanced through a catheter (tube) into the patient' s coronary artery. The standard dose of adenosine is given to the patient through a vein (intravenous). FFR is recorded for two minutes. Before the second measurement, there is a short recovery time for the blood pressure to return to its original values (minimum 5 minutes). After recovery, the second measurement is performed with a similar technique but with a higher dose of adenosine. The FFR results with the standard adenosine dose are used for clinical decision making.

What are the possible benefits and risks of participating?
The study does not involve any extra benefit or risk, as the FFR will be performed as a clinical measurement nevertheless. The only possible consequences will be some discomfort from the use of the higher adenosine dose.

Where is the study run from?
Skane University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2015 to January 2016

Who is funding the study?
Not provided at time of registration

Who is the main contact?
David Sparv
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Assessment of increasing intravenous adenosine dose in fractional flow reserve: a non-randomized trial

Study objectives
Effects of increased adenosine dose in the assessment of fractional flow reserve (FFR) were studied in relation to FFR results, hemodynamic effects and patient discomfort. FFR requires maximal hyperemia mediated by adenosine. Standard dose is 140 µg/kg/min administrated intravenously. Higher doses are commonly used in clinical practice, but an extensive comparison between standard intravenous dose and a high dose (220 µg/kg/min) has previously not been performed.

The primary objective was to study the effects of increased dose intravenous adenosine in FFR. Secondary objectives were to study the hemodynamic effects and patient discomfort of increased adenosine dose in patients with or without caffeine consumption prior to FFR.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics review board of Lund University, 01/12/2012, ref: Dnr 2012/216

Study design
Prospective non-randomized trial with an open-label design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
Following coronary angiography and intracoronary administration of 200µg Nitroglycerin, a 0.014-inch pressure guide wire (Primewire Prestige®/Verrata® Pressure Guide Wire, Volcano Corporation, San Diego, CA, US) was advanced through a 6-F guide catheter into the coronary artery, calibrated and subsequently advanced distal of the lesion. The infusion of intravenous adenosine (Adenosin Life Medical 5mg/ml, Life Medical Sweden AB) was started at a weight-adjusted rate, equivalent to standard dose 140 µg/kg/min and terminated when the two minutes measurement was completed. The agent was administrated through a peripheral intravenous line. FFR was recorded for two minutes (±5 seconds) and calculated by the Volcano CORE™ integrated system with the S5I® software and Case Manager (Volcano Corporation, San Diego, CA, US). Prior to the second measurement, a recovery time was mandatory for the pressure curve to return to baseline values (minimum 5 minutes). After recovery, the second measurement was performed with similar FFR technique and an intravenous adenosine infusion of 220 µg/kg/min. FFR was considered significant if <0.80. The FFR results of standard dose were used for clinical decision of revascularization. A >0.02 drift of the FFR-wire was considered clinical relevant, and if this occurred, a new calibration was performed. Consumption of caffeine was defined as a minimum of 200 ml filter coffee consumed <6h prior to FFR. The patients' coffee intake ranged between 200-400 ml.

Intervention Type
Device

Primary outcome measure
Fractional Flow Reserve values, measured as described above after each dose

Secondary outcome measures
Discomfort, measured using the Visual Analogue Scale straight after FFR

Overall study start date
01/09/2012

Completion date
29/01/2016

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Borderline-significant coronary stenosis (indication for FFR according to ESC Guidelines)
3. Signed informed consent prior to enrollment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
85

Total final enrolment
75

Key exclusion criteria
1. Allergy to adenosine or contrast media
2. Baseline mean arterial pressure <60 mmHg
3. Baseline heart rate <50 bpm
4. Pharmacologically treated asthma
5. Chronic obstructive pulmonary disease equivalent to GOLD classification III and IV
6. Confusion or inability to comprehend the study information

Date of first enrolment

10/01/2013

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Skane University Hospital
Lund
Sweden
SE 22185

Sponsor information

Organisation
Lund University

Sponsor details
Department of Cardiology
22185
Lund
Sweden
22185

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/012a77v79

Funder(s)

Funder type
University/education

Funder Name
Lunds Universitet

Alternative Name(s)
Lund University, Universitas Lundensis, Universitas Gothorum Carolina, Royal Caroline Academy, Regia Academia Carolina, Lund University | Lund, Sweden | LU, Lunds universitet, LU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Results and Publications

Publication and dissemination plan
Original manuscript submitted November 2016.

Intention to publish date
29/01/2017

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are available from David Erlinge (David.Erlinge@med.lu.se) on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/02/2017	27/11/2020	Yes	No