Fractional Flow Reserve versus angiography for multivessel evauation (FAME 3) trial. A comparison of fractional flow reserve guided percutaneous coronary intervention and coronary artery bypass graft surgery in patients with multivessel coronary artery disease.

Published: 14-08-2014
Last updated: 20-04-2024

The primary objective of the FAME 3 Trial is to demonstrate that FFR-guided PCI is noninferior to coronary artery bypass graft surgery in patients with multivessel CAD.

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

Summary

ID

NL-OMON44384

Source
ToetsingOnline

Brief title
FFR guided PCI versus coronary bypass surgery.

Condition

- Coronary artery disorders

Synonym
Coronary artery disease, coronary atherosclerosis, narrowings in the coronary arteries.

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Restricted institutional grants van de firma Medtronic;St. Jude Medical en de Stichting Vrienden van het Hart Zuidoost Brabant.,zie boven G1

Intervention

Keyword: CABG, Coronary Artery Disease (three vessel disease), FFR, PCI

Outcome measures

Primary outcome

Death, myocardial infarction, any repeat revascularization, stroke

Secondary outcome

-Individual components of the primary endpoint.

-Bleeding complications, stent thrombosis, arrhythmia, acute renal failure,

length of hospital stay, cost

Study description

Background summary

Bypass graft surgery (CABG) is recommended over percutaneous coronary intervention (PCI) for patients with multivessel coronary artery disease (MVD). In practice, there is increasingly interest to perform PCI in these patients.

Study objective

The primary objective of the FAME 3 Trial is to demonstrate that FFR-guided PCI is noninferior to coronary artery bypass graft surgery in patients with multivessel CAD.

Study design

Open, randomized, controlled trial

Intervention

Coronary artery bypass surgery (CABG) versus percutaneous coronary intervention (PCI)

Study burden and risks

CABG will be performed as per clinical routine at each participating center. Patient who will be randomized to PCI will not undergo CABG thereby reducing the burden on those patients.

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

Patients with angina pectoris or evidence of myocardial ischemia, age >21 years, with three vessel coronary artery disease and able to provide written informed consent.

Exclusion criteria

- cardiogenic shock
- recenty myocaridal infarction
- concommitant need foor valve surgery or carotic surgery
- poor left ventricular injection fraction
- other serious concommitant disease.

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:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	155
Type:	Anticipated

Ethics review

Approved WMO

Date:	14-08-2014

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-11-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-12-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-01-2019
Application type:	Amendment
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
CCMO	NL48741.060.14