

Trial of Invasive versus Medical therapy of Early coronary artery disease in Diabetes Mellitus

Submission date 25/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/06/2015	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Trial of Invasive versus Medical therapy of Early coronary artery disease in Diabetes Mellitus

Acronym

TIME-DM

Study objectives

Early detection and treatment of silent coronary artery disease (CAD) in diabetic patients may be beneficial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received 28/11/2003

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Early asymptomatic coronary artery disease in diabetic patients

Interventions

A randomized prospective study of medical therapy versus invasive evaluation of CAD and subsequent revascularization

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Cardiac death, myocardial infarction, onset of angina, or hospitalization (for acute coronary syndrom or symptomatic need for revascularization).
Myocardial perfusion changes over time: Evolution of ischemic burden and overall abnormality.

Secondary outcome measures

Angina class, quality of life, impact of medical therapy.
Myocardial perfusion single photon emission computed tomography (SPECT) variables. Left ventricular ejection fraction, volumes.

Overall study start date

01/05/2004

Completion date

31/12/2008

Eligibility

Key inclusion criteria

Patients with diabetes type 2, asymptomatic with respect to angina, no prior coronary artery disease; high risk profile for coronary artery disease (pathologic electrocardiogram [ECG], peripheral vascular disease, microalbuminuria, cardiac autonomic neuropathy, retinopathy, or more than one additional risk factor for CAD).

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

At least 400

Key exclusion criteria

Concomitant disease with prognosis less than 3 years survival. Older than 75 years. End stage renal disease or dialysis.

Date of first enrolment

01/05/2004

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Switzerland

Study participating centre
University Hospital
Basel
Switzerland
CH-4031

Sponsor information

Organisation

University Hospital Basel - Department of Cardiology (Switzerland)

Sponsor details

Petersgraben 4
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Sponsor type

University/education

ROR

<https://ror.org/04k51q396>

Funder(s)

Funder type

Industry

Funder Name

Swiss National Science Foundation

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Funder Name

Schweizerische Herzstiftung

Alternative Name(s)

Swiss Heart Foundation, Fondation Suisse de Cardiologie, Fondazione Svizzera di Cardiologia, HerzstiftungCH

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Funder Name

Pfizer

Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Roche

Alternative Name(s)

F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Funder Name

Takeda

Funder Name

Haider

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2014		Yes	No