

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

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

### 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

**Study type(s)**

Treatment

**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(s)**

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.

**Key secondary outcome(s)**

Angina class, quality of life, impact of medical therapy.

Myocardial perfusion single photon emission computed tomography (SPECT) variables. Left ventricular ejection fraction, volumes.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

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, The Swiss National Science Foundation (SNSF), 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, Pfizer Inc

**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., Roche Holdings, Inc.

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

Switzerland

**Funder Name**

Takeda

**Funder Name**

Haider

**Results and Publications**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

## Study outputs

Output type

[Results article](#)

Details  
results

Date created

01/10/2014

Date added

Peer reviewed?

Yes

Patient-facing?

No