BAsel Stent KostenEffektivitaets Trial (Basel Stent cost-effectiveness trial)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
26/10/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
03/11/2006	Completed	[X] Results		
Last Edited 15/11/2007	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Acronym

BASKET (BAsel Stent KostenEffektivitaets Trial)

Study objectives

Drug Eluting Stents (DES) are not cost-effective in a real world setting when compared to bare metal stents.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the local ethics committee of the University of Basel, March 27, 2003.

Study design

Prospective randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Coronary artery disease

Interventions

PCI in a real world setting (chronic and acute disease). Patients randomised 2:1 to drug eluting versus bare metal stents.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Six month cost-effectiveness with effectiveness defined as reduction of major adverse cardiac events - i.e., cardiac death, non-fatal myocardial infarction and target vessel revascularisation.

Secondary outcome measures

- 1. Mortality from other cause, target vessel ischemia by myocardial perfusion Single Photon Emission Computed Tomography (SPECT).
- 2. Effectiveness of DES in patients with myocardial infarction and saphenous vein graft disease.
- 3. Cost-effectiveness as defined above after 18 and 36 months.

Overall study start date

01/05/2003

Completion date

31/05/2004

Eligibility

Key inclusion criteria

Coronary artery disease suitable for interventional therapy.

All patients referred for cardiac catheterisation and subsequent Percutaneous Coronary Intervention (PCI) irrespective of clinical indication, who are able to provide written informed consent.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

826

Key exclusion criteria

- 1. In-stent-restenosis
- 2. Target vessel diameter equal to or greater than 4 mm
- 3. No informed consent

Date of first enrolment

01/05/2003

Date of final enrolment

31/05/2004

Locations

Countries of recruitment

Switzerland

Study participating centre Cardiology Department

Basel Switzerland CH-4031

Sponsor information

Organisation

University Hospital Basel (Switzerland)

Sponsor details

Petersgraben 4 Basel Switzerland CH-4031

Sponsor type

Hospital/treatment centre

Website

http://www.universitaetsspital-basel.ch/

ROR

https://ror.org/04k51q396

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital, Basel (Switzerland)

Funder Name

Cardiac Research Foundation, Basel (Switzerland)

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	01/09/2005	Yes	No
Other publications	-month cost-effectiveness analysis:	03/11/2007	Yes	No