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

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

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

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