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Evaluation of late clinical events after drug-eluting versus bare-metal stents in patients at risk

Submission date 18/01/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/02/2007	**Overall study status** Completed	
Last Edited 17/12/2015	**Condition category** 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
Evaluation of late clinical events after drug-eluting versus bare-metal stents in patients at risk: BAsel Stent Kosten Effektivitäts Trial - PROspective Validation Examination

Acronym
BASKET-PROVE

Study objectives
The recent findings and analyses of the BAsel Stent Kosten Effektivitäts Trial (BASKET) and the Basel Stent Cost-effectiveness Trial - LAte Thrombotic Events trial (BASKET-LATE) are the basis for two relevant questions which will be addressed prospectively in BASKET-PROVE. The aims of BASKET-PROVE are therefore:
1. To validate findings of BASKET/BASKET-LATE, i.e. that patients with large native vessel stenting (more than or equal to 3.0 mm stents only) do not clinically benefit from Drug Eluting Stents (DES) regarding cardiac death/non-fatal Myocardial Infarction (MI) compared to a third generation Bare Metal Stent (BMS) over an 18 months observation period and may be associated even with a certain small late harm (i.e. comparison of Cypher-Select® versus Vision® stents)
2. To evaluate whether a stent with the same cobalt-chromium platform as Vision® but with a lower dose of a limus drug (Xience®, coated with Everolimus) has a similar late outcome as the third generation BMS Vision® stent (no increase in late cardiac death/MI)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee (Ethikkommission beider Basel), 11/01/2007, ref: 327/06

Study design
Prospective randomised open-label muticentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
Patients will be randomised to:
1. 1:1 to PCI and Stent placement with Cypher-Select® (standard first generation DES) versus Vision® (third generation cobalt-chromium BMS)
2. 1:1 to Xience® (DES with a lower dose of a limus drug, i.e. Everolimus [Abbott Vascular, Abbott Laboratories, Illinois, US]).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Freedom of combination of:
1. Cardiac death (all death not clearly of extra cardiac origin)
2. Documented non-fatal MI (according to the current European Society of Cardiology [ESC]-guidelines after 24 months

Secondary outcome measures
1. Non-MI related Target Vessel Revascularisation (TVR)
2. Major Adverse Cardiac Events (MACE) = primary outcomes and non-MI related TVR
3. Primary outcomes up to 18 and 36 months (for comparison with BASKET and BASKET-LATE)
4. Components of the primary outcomes
5. Non-cardiac death (total death)
6. Major non-Coronary Artery Bypass Graft (CABG) bleeding (need for surgery, blood transfusions, cerebral haemorrhages) during dual antiplatelet therapy (up to twelve months) - net clinical benefit = primary outcomes and bleeding
7. Subgroups with:
a. diabetes
b. acute coronary syndrome
c. ST-elevation MI
d. need for GlycoProtein (GP) IIb/IIIa inhibitors
e. lesions more than 25 mm

Overall study start date
01/02/2007

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. All comers, 24 hours a day, seven days a week, irrespective of indication for Percutaneous Coronary Intervention (PCI)
2. With the need for large (more than or equal to 3.0 mm stents only) native vessel stenting

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
2400

Key exclusion criteria
1. In-stent-restenosis
2. Bypass graft disease
3. Main stem disease to be stented
4. Cardiogenic shock
5. Planned surgery within the next six months
6. Oral anticoagulation needed (artificial heart valves, atrial fibrillation)
7. No compliance expected
8. Enrolled in another study
9. No consent

Date of first enrolment
01/02/2007

Date of final enrolment
16/05/2008

Locations

Countries of recruitment
Denmark

Norway

Switzerland

Study participating centre
University Hospital Basel
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Sponsor information

Organisation
University Hospital Basel (Switzerland)

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Government

Funder Name
The Swiss National Foundation for Research (Switzerland) (study grant applied for)

Funder Name
Additional funding by unrestricted grants from third parties will be searched for.

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	03/10/2013		Yes	No
Results article	results	01/10/2015		Yes	No