

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/12/2015	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

Protocol serial number
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 multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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

Basel

Switzerland

4031

Sponsor information

Organisation

University Hospital Basel (Switzerland)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes