Late clinical events after paclitaxel- vs. zotarolimus-eluting stents in patients with small vessel stenting

Submission date	Recruitment status	Prospectively registered
31/01/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
06/03/2007	Completed	Results
Last Edited	Condition category	Individual participant data
09/05/2016	Circulatory System	Record updated in last year

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

BAsel Stent Kosten Effektivitäts Trial - late clinical events in patients with SMALL vessel stenting

Acronym

BASKET-SMALL

Study objectives

Hypothesis as of 09/05/2016: The question, whether late outcome may be improved further by a new generation of drug-eluting stent (DES), the zotarolimus-eluting Endeavor® stent compared to a first generation DES, the Taxus® stent, is not known and will be addressed in the prospective randomized BASKET-SMALL pilot study.

Specific aims of BASKET-SMALL pilot will, therefore, be:

- 1. To compare two drug-eluting stents, the first generation Taxus® stent with the second generation Endeavor® stent in patients with at least one stent <3.0 mm on clinical outcome after 24 months.
- 2. To compare these data to the findings of similar patients in BASKET-LATE (historical control) treated with the BMS Vision®.

Original hypothesis:

The question, whether late outcome may be improved further by a new generation of drugeluting stent (DES) with a totally absorbable polymer such as the Co-Star® stent (Conor Med System, Menlow Park, CA, USA) which is CE marketed and in use in Basel since 2006 compared to a first generation DES with the same drug coating, the Taxus® stent, is not known and will be addressed in the prospective randomized BASKET-SMALL pilot study.

Specific aims of BASKET-SMALL pilot will, therefore, be:

- 1. To compare two paclitaxel-eluting stents, the first generation Taxus® stent with the second generation Co-Star® stent with a totally absorbable polymer in patients with at least one stent <3.0 mm on clinical outcome after 18 months.
- 2. To compare these data to the findings of similar patients in BASKET-LATE (historical control) treated with the BMS Vision®.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethikkommission beider Basel, 11/12/2006, ref: 326/06

Study design

Prospective randomized open-label single-center trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Coronary artery diesease

Interventions

Interventions as of 09/05/2016:

Randomization will be 1:1 to Taxus® (standard 1st generation DES with paclitaxel) versus Endeavor® (2nd generation DES with zotarolimus).

Origianl interventions:

Randomization will be 1:1 to:

Taxus® (standard 1st generation DES) versus Co-Star® (DES with biodegradable polymer)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Primary outcome measures as of 09/05/2016:

Absence of both major adverse cardiac events (MACE), i.e., of the following:

- 1. Cardiac death (all death not clearly of extra cardiac origin)
- 2. Documented non-fatal Myocardial Infarction (MI) (according to the current European Society of Cardiology

[ESC]-guidelines)

3. Non-MI-related target vessel revascularization (TVR)

All after 18 months

Original primary outcome measures:

Absence of both of the following:

- 1. Cardiac death (all death not clearly of extra cardiac origin)
- 2. Documented non-fatal Myocardial Infarction (MI) (according to the current European Society of Cardiology

[ESC]-guidelines) after 18 months

Key secondary outcome(s))

Secondary outcome measures as of 09/05/2016:

- 1. Primary end-point events up to 12 and 24 months
- 2. Non-cardiac death (total death)
- 3. Major non-coronary artery bypass graft (CABG) bleeding (need for surgery, blood transfusions, cerebral hemorrhages) during dual antiplatelet therapy (up to 12 months)
- 4. Net clinical benefit = primary end-point + bleeding

Subgroups with:

- a. Diabetes
- b. Acute coronary syndrome
- c. ST-elevation myocardial infarction (MI)
- d. Need for glycoprotein (GP) IIb/IIIa inhibitors
- e. Lesions >25 mm
- f. All stents < 3mm

Original secondary outcome measures:

- 1. Non-MI related target vessel revascularization (TVR)
- 2. Major adverse cardiac events (MACE) = primary end-point events + non-MI related TVR
- 3. Primary end-point events up to 12 and 24 months
- 4. Non-cardiac death (total death)

- 5. Major non-coronary artery bypass graft (CABG) bleeding (need for surgery, blood transfusions, cerebral hemorrhages) during dual antiplatelet therapy (up to 12 months) net clinical benefit = primary end-point + bleeding.
- 6. Subgroups with:
- a. Diabetes
- b. Acute coronary syndrome
- c. ST-elevation myocardial infarction (MI)
- d. Need for glycoprotein (GP) IIb/IIIa inhibitors
- e. Lesions >25 mm
- f. All stents < 3mm

Completion date

31/12/2009

Eligibility

Key inclusion criteria

- 1. All comers, 24 hours a day, 7 days a week, irrespective of indication for percutaneous coronary intervention (PCI)
- 2. With the need of small vessel stenting (at least one stent <3.0 mm)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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 6 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

01/03/2007

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Switzerland

Study participating centre Department of Cardiology

Basel Switzerland 4031

Sponsor information

Organisation

University Hospital Basel

ROR

https://ror.org/04k51q396

Funder(s)

Funder type

Charity

Funder Name

Foundation for Cardiovascular Research (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration