ISRCTN09125734 https://doi.org/10.1186/ISRCTN09125734

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

Submission date 31/01/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 06/03/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/05/2016	**Condition category** Circulatory System	[_] Individual participant data [_] 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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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 drug-eluting 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

Primary study design
Interventional

Study design
Prospective randomized open-label single-center trial

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
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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