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Interventional therapy of bifurcation lesions: A flow-guided concept to treat side branches in bifurcation lesions - a prospective randomized clinical study (THUEringer BIfurcation Study, THUEBIS-Study)

Submission date 23/12/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/02/2008	**Overall study status** Completed	
Last Edited 06/01/2010	**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

001

Study information

Scientific Title

Acronym
THUEBIS Study

Study objectives
Simple Percutaneous Coronary Intervention (PCI) of bifurcation lesions is not inferior to complex PCI

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee, Thüringen Health Centre (Landesärztekammer Thüringen), approved on 25 June 2003 (ref: kl/1065/03/111)

Study design
Prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Coronary bifurcation lesion

Interventions
Complex vs simple PCI

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Target Lesion Revascularization (TLR) at 6 months

Secondary outcome measures
1. Incidence of binary restenosis >50% (MB) at 6 months
2. Calculated late-luminal loss evaluated by Quantitative Coronary Angiography (QCA) 6 months after PCI
3. Incidence of Target Vessel Revascularization (TVR) and Major Adverse Cardiac Events (MACE) at 6 months

Overall study start date
01/09/2004

Completion date
01/12/2006

Eligibility

Key inclusion criteria
1. Male or female patients older than 18 years of age
2. Diagnosis of stable angina or silent ischemia
3. Presence of a de novo, true coronary bifurcation lesion, defined as stenosis >50% in both the Main Branch (MB) and the ostium of the Side Branch (SB). Both branches were required to have a Thrombolysis In Myocardial Infarction (TIMI) flow of at least 2 or 3 as well as a reference vessel size >2.25 mm by visual estimation or a relevant SB which the operator would not have wanted to loosen during the procedure. If two commensurate vessels were present, the main branch was defined as the largest of the two vessels involved.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110

Key exclusion criteria
1. A myocardial infarction in the 24 hours preceding treatment (STEMI and NSTEMI)
2. Stenosis of the left main coronary artery unprotected by a graft
3. Cardiogenic shock
4. Angiographically visible thrombus within the target lesion, restenosis or total occlusion of the

target lesion
5. Life expectancy <1 year
6. Suspected intolerance to paclitaxel, aspirin or clopidogrel

Date of first enrolment
01/09/2004

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
Germany

Study participating centre
Hetzelstift
Neustadt an der Weinstrasse
Germany
67434

Sponsor information

Organisation
Berka Clinic, Department of Cardiology (Zentralklinik Bad Berka, Klinik für Kardiologie) (Germany)

Sponsor details
Robert-Koch-Allee 9
Bad Berka
Germany
99437

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00zfe1b87

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Berka Clinic, Department of Cardiology (Germany)

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	01/12/2009		Yes	No