

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/02/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/01/2010	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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