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Balloon angioplasty versus stenting with nitinol stents in the superficial femoral artery

Submission date	Recruitment status	[_] Prospectively registered
23/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/05/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/10/2009	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Martin Schillinger

Contact details
Medical University Vienna
General Hospital Department of Internal Medicine II, Angiology
Waehringer Guertel 18-20
Vienna
Austria
A 1090
martin.schillinger@meduniwien.ac.at

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00281060

Secondary identifying numbers
EK 164/2003

Study information

Scientific Title

Acronym
Absolute Trial

Study objectives
Primary stenting with self-expanding nitinol stents may improve patency after endovascular treatment of superficial femoral artery obstructions compared to balloon angioplasty with optional stenting

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethics Committee of the Medical University of Vienna and Vienna General Hospital, reference number: EK 164/2003

Study design
1:1 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
Peripheral artery disease, superficial femoral artery stenosis or occlusion

Interventions
Group 1: primary stenting
Group 2: Percutaneous transluminal angioplasty (PTA) (balloon angioplasty) with optional secondary stenting

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Angiographic restenosis at six months

Secondary outcome measures
1. Restenosis by duplex ultrasound at 3, 6 and 12 months
2. Walking distance on the treadmill at 3, 6 and 12 months
3. Ankle brachial index at 3, 6 and 12 months
4. Stent fractures at 6 and 12 months

Overall study start date
01/06/2003

Completion date
31/07/2005

Eligibility

Key inclusion criteria
1. Symptomatic peripheral artery disease - Rutherford stages 3 to 5
2. >50% Stenosis of the ipsilateral superficial femoral artery
3. Lesion length >30 mm
4. At least one patent crural runoff vessel

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
110 patients planned

Key exclusion criteria
1. Acute critical limb ischemia
2. Previous ipsilateral bypass surgery or ipsilateral superficial femoral artery (SFA) stenting
3. Untreated inflow disease
4. Known intolerance to clopidogrel, aspirin or radiocontrast

Date of first enrolment
01/06/2003

Date of final enrolment
31/07/2005

Locations

Countries of recruitment
Austria

Study participating centre
Medical University Vienna
Vienna
Austria
A 1090

Sponsor information

Organisation
Medical University Vienna (Austria)

Sponsor details
c/o Prof Erich Minar
Waehringer Guertel 18-20
Vienna
Austria
A 1090
+43 (0)1 40400 4670
martin.schillinger@meduniwien.ac.at

Sponsor type
University/education

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
University/education

Funder Name
The trial was funded by the Medical University of Vienna and Vienna General Hospital (Austria)

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	04/05/2006		Yes	No