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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2006		☐ 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

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00281060

Protocol serial number

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

Study type(s)

Treatment

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(s)

Angiographic restenosis at six months

Key secondary outcome(s))

- 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

Completion date

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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