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COvered Balloon Expandable Stent Trial

Submission date 26/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2006	**Overall study status** Completed	
Last Edited 06/08/2021	**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
N/A

Study information

Scientific Title

COvered Balloon Expandable Stent Trial

Acronym
COBEST

Study objectives
Does covered stent in aortoiliac occlusive disease have the same patency or even better patency rate than bared stent?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval received from the following hospitals:
1. Royal Perth Hospital (Australia)
2. St Vincents Public Hospital (Australia)

The following hospitals are pending ethical approval for participation in the COBEST trial:
St Vincents Private Hospital (Australia)
Royal Prince Alfred Hospital (Australia)
Hollywood Private Hospital (Australia)

Study design
The study is an interventional, prospective, multicentre, randomised, controlled non-inferiority trial of V12 covered stent versus bare stent.

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
Iliac artery occlusive disease

Interventions
V12 covered stent versus bare stents.

Runoff vessels:
The superficial and deep femoral arteries are the runoff vessels for iliac artery procedures, and the tibial arteries are the runoff vessels for femoral or popliteal procedures. The scoring system below will be used:
1. Two points will be given to a widely patent Superficial Femoral Artery (SFA) or Profunda

femoris (2)
2. One point for a diseased but patent vessel (SFA or profunda femoris) (1)
3. No points for an occluded vessel (SFA or profunda femoris) (0)
Thus giving a range from zero to four, where four represents an excellent run-off.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Comparison, between the two treatment groups (V12 covered stent versus bare stents) of:
1. Primary patency
2. Assisted primary patency

Secondary outcome measures
Secondary objectives:
1. Any amputation above the ankle
2. Ankle Brachial Index (ABI) changes from baseline

Overall study start date
20/02/2006

Completion date
30/08/2007

Eligibility

Key inclusion criteria
1. Informed consent obtained
2. Patient aged 18 years or over and under 80 years
3. Patients with TransAtlantic Society Consensus (TASC) type B, C and D lesions
4. Haemodynamically significant dissections after angioplasty
5. Haemodynamically significant recurrent stenosis after angioplasty

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
154

Total final enrolment
125

Key exclusion criteria
1. Life expectancy of less than 12 months
2. Patients with uncontrolled hypertension
3. Patient with TASC type A lesion
4. Pregnant women or women of childbearing potential who are not following an effective method of contraception
5. Prior enrolment in this trial, patients who had any procedure performed at the aortoiliac level
6. Patients with extensive common femoral artery disease or who have had multiple groin procedures
7. Contradiction to aspirin or clopidogrel usage
8. Patients with superficial and profunda femoral arteries occluded
9. Mental condition rendering the subject unable to understand the nature, scope, and possible consequences of the study, or language barrier such that the subject being unable to give informed consent
10. Uncooperative attitude or potential for non-compliance with the requirements of the protocol making study participation impractical

N.B. In patients with a plasma/serum creatinine of more than 250 - 300 µmol/L, iodinated contrast is contraindicated and should be avoided.

Date of first enrolment
20/02/2006

Date of final enrolment
30/08/2007

Locations

Countries of recruitment
Australia

Study participating centre
Vascular Unit
Perth
Australia
6000

Sponsor information

Organisation
Atrium Australia (Australia)

Sponsor details
Julia Agars
Atrium Australia
PO Box 420
Spit junction
New South Wales
Australia
2088

Sponsor type
Industry

Website
http://www.atriummed.com

ROR
https://ror.org/03ds2he10

Funder(s)

Funder type
Industry

Funder Name
Atrium Australia (Australia)

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		09/09/2011	06/08/2021	Yes	No