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Drug eluting balloon venoplasty in arterio--venous fistula stenosis

Submission date	Recruitment status	[_] Prospectively registered
20/01/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/01/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/10/2021	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys do not work properly. In a healthy person, the kidneys are responsible for filtering out the waste products and excess water in the blood, and converting them into urine. In patients suffering from CKD, the kidneys are unable to do this, and so the body is unable to get rid of the waste products building up in the blood. Haemodialysis is one of the most common treatments for CKD patients, and involves diverting the blood into an external machine so that it can be “cleaned”, before being returned to the body. It requires direct access to the circulatory system (blood stream) and the best option for this is a by creating an arterio-venous fistula (AVF), which is made by surgically joining an artery and a vein in the arm. AVFs have a limited lifespan, and over time can become narrowed (stenosed) or blocked (thrombosed). The fistula can be used for haemodialysis again if it is “re-opened”. This is done by inflating a small balloon inside the fistula to flatten any blockages against the artery wall (fistuloplasty). In many cases however, the fistula re-narrows and becomes blocked again (restenosis). New techniques have been developed where the balloon used in the fistuloplasty is coated in a drug, such as Paclitaxel (drug-eluting balloon, DEB). This drug slows the growth of new smooth muscle cells in the vessel wall that may lead to re-narrowing (restenosis). The aim of this study is to find out whether a DEB is more effective than standard balloons (with no drug coating) at slowing down and preventing restenosis.

Who can participate?
Adults who have a narrowed AVF, which has been in use for at least 1 month.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive the standard fistuloplasty procedure, in which a plain balloon is inflated until the fistula becomes wide enough to become usable. Participants in the second group receive the standard fistuloplasty procedure, in which a balloon coated in a drug called paclitaxel is used. Participants attend follow-up appointments 3, 6 and 12 months after their operation so that the openness (patency) of the fistula can be monitored.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Queen Elizabeth Hospital, Birmingham (UK)

When is the study starting and how long is it expected to run for?
January 2016 to October 2018

Who is funding the study?
Boston Scientific Corporation (USA)

Who is the main contact?
Dr Rob Jones, robert.jones@uhb.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02902094

Secondary identifying numbers
20313

Study information

Scientific Title

Improving outcomes in fistula intervention: A prospective, patient blinded, phase III, randomised controlled trial of drug eluting balloons in the angioplasty of native haemodialysis access arterio-venous fistula outflow stenosis

Acronym
DeVA

Study objectives
The aim of this study is to investigate whether the use of drug eluting balloons (DEB's) during angioplasty can reliably reduce the rate of re-stenosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Medical Research Ethics Committee, 05/11/2015, ref: 15/EM/0483

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Renal failure

Interventions
Participants are randomised into one of two arms.

Intervention arm: Participants receive a fistuloplasty procedure using a paclitaxel-coated balloon.
Control arm: Participants receive a fistuloplasty procedure using an un-coated balloon.

Participants in both groups are followed up at 3, 6 and 12 months post-fisuloplasty.

Intervention Type
Other

Phase

Phase III

Primary outcome measure
Presence of at least 50% restenosis of index lesion requiring re-intervention is measured at 3, 6 and 12 months.

Secondary outcome measures
1. Fistula failure rate (thrombosis or non-salvageable) is measured at 3, 6 and 12 months
2. Re-intervention rate due to clinical or paraclinical indictions (without 50% restenosis) is measured at 3, 6 and 12 months

Overall study start date
15/01/2016

Completion date
30/04/2020

Eligibility

Key inclusion criteria
1. Arteriovenous (AV) fistulas with stenosis requiring percutaneous angioplasty identified on routine diagnostic imaging or causing clinical concern on dialysis
2. Fistula has been in use for at least 1 month and is more than 6 weeks old
3. Brachiocephalic AV fistula
4. Brachiobasilic AV fistula
5. Radiocephalic AV fistula (both proximal and distal)
6. Aged 18 years or over
7. Index lesion is less then the length of the DEB, and the reference vessel diameter is appropriate for treatment with the size range of DEB (4mm - 8mm diameter)
8. Capacity to give valid informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 186; UK Sample Size: 186

Total final enrolment
92

Key exclusion criteria

1. Allergy to iodinated Intravenous contrast
2. Allergy to Paclitaxel
3. Prosthetic grafts
4. Long or tandem lesions that cannot be treated with a single DEB
5. Thrombosed Arterio-Venous fistulas
6. Women who are breastfeeding, pregnant or intending to become pregnant
7. Participants of child-bearing age who are unwilling to use a reliable form of contraception for the duration of the study

Date of first enrolment
15/01/2016

Date of final enrolment
30/04/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
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B15 2TH

Sponsor information

Organisation
University Hospital Birmingham NHS Foundation Trust

Sponsor details
Renal Department
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Government

Funder Name
Boston Scientific Corporation

Alternative Name(s)
Boston Scientific, Boston Scientific Corp., BSC

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No