

# Drug eluting balloon venoplasty in arterio-venous fistula stenosis

<b>Submission date</b> 20/01/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/01/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 11/10/2021	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Contact name**  
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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-fistuloplasty.

**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 indications (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 than 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

United Kingdom

B15 2TH

## **Sponsor information**

**Organisation**

University Hospital Birmingham NHS Foundation Trust

**Sponsor details**

Renal Department

Queen Elizabeth Hospital

Edgbaston

Birmingham

England

United Kingdom

B15 2TH

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No