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Comparison of drug-eluting and plain balloon angioplasty in the treatment of stenosis of vascular access for dialysis

Submission date
08/11/2022

Recruitment status
No longer recruiting

Registration date
01/12/2022

Overall study status
Completed

Last Edited
28/12/2022

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dialysis access circuit often develops stenosis and becomes unusable. Dilation of the stenosis using a wire and balloon inserted in the access is required to restore its patency. The aim of this study is to evaluate if adult patients with stenosis in dialysis vascular access would benefit from the use of a drug-eluting balloon.

Who can participate?
Adult patients with a clinically mature dialysis fistula already used for hemodialysis

What does the study involve?
Patients, who consent to participate, will receive additional treatment for the stenosis using a balloon catheter (drug-eluting balloon or plain balloon according to the randomization group). The drug-eluting balloon should slow down the recurrence of the stenosis and may prolong the usability of the access circuit. Participants will be asked to visit the facility for follow-up angiography at 3, 6, 9, and 12 months after the initial procedure or earlier if the access circuit develops stenosis (suspected by the physician or detected by ultrasound).

What are the possible benefits and risks of participating?
Any benefit from participation in this study is uncertain. Participation in this study does not involve additional risks compared to angioplasty with a "plain" balloon.

Where is the study run from?
Charles University in Prague (Czech Republic)

When is the study starting and how long is it expected to run for?
October 2018 to November 2021

Who is funding the study?
First Faculty of Medicine, Charles University and General University Hospital in Prague (Czech Republic)

Who is the main contact?
Associate Prof Andrea Burgetova, andrea.burgetova@vfn.cz (Czech Republic)

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparison of drug-eluting and plain balloon angioplasty in the treatment of stenosis of vascular access for dialysis

Study objectives
The use of a drug-eluting balloon for angioplasty with stenosis in vascular access for dialysis results in better primary patency rates than plain balloon angioplasty alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/10/2018, Ethics Committee of the General University Hospital in Prague (Na Bojišti 1, 3. Patro 128 08 Praha 2, Czech Republic; +420 224 964 131; eticka.komise@vfn.cz), ref: 1440 /18 S-IV

Study design
Single-center prospective single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment with stenosis in the vascular access for dialysis in adult patients using percutaneous transluminal angioplasty

Interventions
The aim of this study was to evaluate if adult patients with stenosis in dialysis vascular access would benefit from the use of a drug-eluting balloon.
The patients are referred from dialysis centers across the Czech Republic for angiography (and percutaneous transluminal angioplasty [PTA]) of the access circuit due to signs of its dysfunction. Exclusion and inclusion criteria are verified before and during the angiography. A follow-up angiography every 3 months up to 1 year (or up to the first PTA) after the index procedure is performed in both groups.

Patients, who consent to participate, will receive additional treatment for the stenosis using a balloon catheter (drug-eluting balloon or plain balloon according to the permuted block randomization group). The drug-eluting balloon should slow down the recurrence of the stenosis. Participation in this trial does not involve additional risks compared to angioplasty with a "plain" balloon.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Resveratrol-excipient paclitaxel-coated balloon

Primary outcome(s)
Primary patency rates measured using angiography and the need for repeated intervention at 3, 6, 9, 12 months or earlier if requested by the physician

Key secondary outcome(s))
Median time to target lesion re-intervention measured using medical records and angiography at 3, 6, 9, 12 months or earlier if requested by the physician

Completion date
30/11/2021

Eligibility

Key inclusion criteria
1. Aged >18 years old
2. Life expectancy >1 year
3. Clinically mature dialysis fistula (AVG or AVF) already used for hemodialysis with adequate pump speed and dialysis efficacy for at least 4 consecutive sessions with the two-needle technique
4. Signs of fistula dysfunction (absent thrill, low flow, high venous pressure, high pulsatility, needling problems, abnormal pulsatility, abnormal auscultation, extremity edema, etc)
5. Hemodynamically significant (>50%) stenosis in juxta-anastomotic or outflow vein of AVF (excluding central veins defined as veins medial to the lateral margin of the first rib) or in the venous anastomosis, juxta-anastomotic segment or outflow vein in AVG (excluding central veins).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
76

Key exclusion criteria
1. Access circuit thrombosis in the last year
2. History of graft infection
3. Prior use of a drug-eluting balloon catheter in the access circuit
4. In-stent restenosis in bare metal or covered stent
5. Angiography contraindications (e.g. severe contrast media allergy)
6. Two or more distinct significant stenoses in the access circuit

Date of first enrolment
19/10/2018

Date of final enrolment
31/10/2020

Locations

Countries of recruitment
Czech Republic

Study participating centre
Department of Radiology, First Faculty of Medicine, Charles University and General University Hospital in Prague
U Nemocnice 2
Prague 2
Czech Republic
12808

Sponsor information

Organisation
Charles University

ROR
https://ror.org/024d6js02

Funder(s)

Funder type
University/education

Funder Name
lékařská fakulta Univerzity Karlovy (First Faculty of Medicine Charles University)

Alternative Name(s)
The First Faculty of Medicine of Charles University, Charles University in Prague - First Faculty of Medicine, First Faculty of Medicine, Charles University, First Faculty of Medicine Charles University, First Faculty of Medicine of Charles University, First Faculty of Medicine, Charles University in Prague, Univerzita Karlova 1. lékařská fakulta

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Czech Republic

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/12/2022	28/12/2022	Yes	No
Participant information sheet			21/11/2022	No	Yes