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Evaluation of the effectiveness of the ePATH Guided Re-entry Catheter Kit in bypassing a blockage of a leg artery

Submission date	Recruitment status	[ ] Prospectively registered
11/03/2020	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/07/2020	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/01/2022	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Patients who have no blood flow in their leg arteries because they are blocked can be treated via special tubes called catheters that can be inserted into the artery. First an attempt is made to pierce the blockage with a sharp wire that goes inside the catheter. If this is not possible then a wire is passed around the blockage by going inside the wall of the artery. Once past the blockage, the wire needs then to be redirected back into the downstream artery in order to reconnect to the main blood stream, a channel for blood flow that bypasses around the blockage can be made by implanting special tubes called grafts using the wire as a guide. Then blood will flow around the blockage back into the artery to reach the rest of the leg, and solve the problems caused by the blockage. One step in this process, the re-entry of the initial wire back into the vessel past the blockage, can sometimes be extremely challenging. The existing devices to achieve this re-entry can be difficult to use and can miss the artery. The aim of this study is to evaluate a new device, the ePATH Catheter Kit, which incorporates a new method of electronic guidance to assist the doctor to do this more efficiently and accurately.

Who can participate?

Patients aged 18 to 90 who have an artery that needs unblocking (chronic total occlusion of the femoral, popliteal, external iliac or common iliac suitable for endovascular intervention [PTA or peripheral stenting])

What does the study involve?

The treatment will follow the usual course, except the new ePATH Catheter Kit will be used to create a channel around the blockage instead of the existing devices. Once this is done the device will be removed and the treatment will continue unchanged, and the same graft will be implanted as before. The study will be carried out on 10 patients at Northwick Park Hospital in the second part of 2020 by the same doctor who normally carries out this treatment, the patient will not see any change to the care given or the number of hospital visits. The patient will attend the usual 6-week check-up after the treatment and leave the study at that point.

What are the possible benefits and risks of participating?
The potential benefit of this new approach is that the positioning of the wire around the blockage will be quicker, and less likely to miss the artery requiring re-positioning. There is a risk that the new ePATH Catheter Kit will not be any better at positioning the wire, if that happens then an existing device will be used. The new catheter has been thoroughly tested in the factory, but this is the first time it is used in patients which is why it is being used in a carefully observed study.

Where is the study run from?
Northwick Park Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2020 to December 2020

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Dr Robert Dickinson
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Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
274700

Protocol serial number
19IC5677

Study information

Scientific Title
Safety and performance evaluation of the ePATH guided percutaneous re-entry device for guiding the delivery of a guidewire around a chronic total occlusion of lower limb artery

Acronym
eFACTOR

Study objectives
To investigate whether the ePATH Catheter Kit and Display can be used to safely deliver a guidewire that bypasses a CTO.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/05/2020, London - Dulwich Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road. London SE1 6LH, UK; +44 (0)207 104 8241; dulwich.rec@hra.nhs.uk), REC ref: 20/LO/0330

Primary study design
Observational

Study design
Prospective non-randomised single-arm single-centre observational study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vascular disease

Interventions
Percutaneous bypass of Chronic Total Occlusions in arteries of the leg. This involves placing a guidewire around a chronic total occlusion via the sub-intimal space and back into the artery under the electronic guidance of the ePATH system. Subsequently, a graft is delivered over the guidewire and deployed to create a channel for blood perfusion to the distal vasculature. Follow up for 6 weeks.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Measured immediately after the procedure:
1. Incidence of peri-procedural Major Adverse Events
2. Success rate of target lesion crossing defined by crossing with a 0.014 inches guide wire from true lumen to true lumen

Key secondary outcome(s)
Measured immediately after the procedure with the exception of late adverse events:
1. Number of deployment attempts until the guidewire enters true lumen
2. Distance between the distal cap and the re-entry point (using X-ray image post procedure and target catheter tip length as reference)
3. Time from first steps taken to insert the ePATH target catheter into vessel until successful lesion crossing, documented using fluoroscopic images/video timestamps
4, Incidence of late adverse events reported at 6-week follow-up

Completion date
31/12/2020

Reason abandoned (if study stopped)
Participant recruitment suspended and the study was ultimately closed due to public health guidance causing restrictions to study activities

Eligibility

Key inclusion criteria
1. Patient has a chronic total occlusion of the femoral, popliteal, external iliac or common iliac requiring treatment
2. Male or female patient, aged ≥18 and ≤90 years at time of enrolment
3. Suitable for endovascular intervention (PTA or peripheral stenting)
4. Able and willing to give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Any of the following blood disorders, confirmed by the pre-assessment laboratory tests taken as standard of care, within the month before the procedure:
1.1. Anaemia with haemoglobin < 80g/L
1.2. Thrombopaenia with platelets ≤ 50 000/mL
1.3. Coagulation disorder with INR ≥ 1.5
2. If female, patient is pregnant or lactating at the time of enrolment or planning to become pregnant during the study time period
3. Patient has participated in another clinical study involving an investigational drug or investigational device within 30 days prior to enrolment or is scheduled to participate in another clinical study involving an investigational drug or investigational device during the course of this study. Patients enrolled in observational registries not involving investigational drug or investigational device may still be eligible
4. Patient is in custody or an institution
5. Patient has close affiliation with the study site or sponsor (e.g. employee, close relative of an employee)

Date of first enrolment
11/03/2020

Date of final enrolment
01/12/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northwick Park Hospital
LNWH NHS Trust Watford Road
Harrow
London
United Kingdom
HA1 3UJ

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Patient identifiable data will be restricted to the study site, Northwick Park Hospital, and will be in hard copy form. Patients will be asked to consent to their data being used for this study. Requests for access to the datasets should be made to Simon Lewis, Research Governance Manager LNWH NHS Trust, R&D Office, Northwick Park Hospital, Watford Road, Harrow HA1 3UJ, Tel: +44 (0)20 8869 5173, email: simon.lewis4@nhs.net. Anonymised data and summarised data will be made available to the Chief Investigator Dr R J Dickinson, Imperial College.

IPD sharing plan summary
Available on request

Study outputs

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