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Real-world performance evaluation of PreSize Neurovascular medical software in a clinical setting

Submission date
28/01/2022

Recruitment status
No longer recruiting

Registration date
12/05/2022

Overall study status
Completed

Last Edited
23/01/2026

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Stenting is a common treatment for cardiovascular (heart) diseases, such as aneurysms. Stents are small spring-like metallic structures used to strengthen weak blood vessels or open them up when they become clogged. The shape and size of each blood vessel is different so there are many different stents for the doctor to choose from.
The success of the stenting procedure depends on the right fit of the stent in the affected blood vessel. Currently, it is difficult for doctors to predict which stent will give a good fit from looking at the standard brain scans. A company called Oxford Heartbeat has built a computer software (a computer program) called PreSize Neurovascular that can be used by doctors to plan the procedure and help them choose the 'best fit' stent for each patient by creating an accurate 3D image of their blood vessels in the brain.
PreSize Neurovascular software has demonstrated high accuracy in calculating the size of the required stent based on patients' brain scans.
This study tries to understand the benefits of this computer program when used by doctors to help them plan for brain stenting surgeries and how well it works in real-world clinical practice. Oxford Heartbeat will work with hospitals in England and Scotland to collect this information over a period of about 16 months from approximately 100 patients.

Who can participate?
Patients aged 18 years and above who are scheduled to receive treatment for an intracranial aneurysm with one of the flow diverters compatible with PreSize Neurovascular at one of the participating NHS sites.

What does the study involve?
In this study, the patient will not be asked to do anything that is not already part of their usual treatment. The doctor will plan the stenting procedure using their standard method, and then by using the PreSize Neurovascular computer program. The program will prepare a computer model of the patient's blood vessels in the brain based on the scans done in preparation for the procedure. The doctor will practice fitting different stents on the computer model. Once both planning methods are complete your doctor will decide at their own discretion which stent to

use based on either the standard method or the computer program method. After the procedure, the patient will continue to receive the usual treatment as prescribed by the doctor. If the patient agrees to participate, the study doctor and nurses will collect information about their medical care for study analysis, but no information that could identify the patient (e.g., name, NHS number).

What are the possible benefits and risks of participating?
Patients may not benefit directly from participating in this study. With the help of this study, however, the aim is to gain further insights into how future patient outcomes could be improved and NHS costs reduced through the use of the computer software.

Where is the study run from?
There are participating hospitals across the UK (England, Wales and Scotland). The trial is run from Imperial College Trials Unit and Oxford Heartbeat, the company that developed the software, both based in London, UK.

When is the study starting and how long is it expected to run for?
June 2020 to July 2025

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

Who is the main contact?
Investigators and NHS Trusts wishing to express interest in participating in this study please contact presize@imperial.ac.uk
Patients who would like to get more information on participation in the study please contact Chief Investigator Dr Tufail Patankar (tufail.patankar@nhs.net)

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
296470

Central Portfolio Management System (CPMS)
50137

Study information

Scientific Title
Real-world performance evaluation of PreSize Neurovascular medical software in a clinical setting

Acronym
PreSize Neurovascular

Study objectives
PreSize Neurovascular is accurate at simulating stent length when the software is used under real-world conditions and contributes to improved clinical care by increasing surgical efficiency (e.g. by minimising device waste or reducing procedure and planning time).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/08/2021, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; gram.nosres@nhs.scot), REC ref: 21/NS/0104

Primary study design
Interventional

Study design
Non-randomized; Interventional; Design type: Treatment, Process of Care, Device, Imaging, Surgery

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intracranial aneurysm

Interventions
Study design: Post-market, multi-centre, prospective, non-randomised study

Summary of the study procedures:
Study interventional neuroradiologists (INRs) will plan flow diverter (FD) brain stenting procedures on prospectively identified participants using two methods: first using their usual methods, and then using PreSize Neurovascular software. The brain stenting procedures will be conducted as they usually would be but informed by the planning conducted using PreSize Neurovascular. Study participants will be followed-up after 6 months (as well as after 1 year, where possible considering duration of the whole study).

The study will also involve the collection of data on historical cases performed by the participating INRs as a benchmark for the outcomes collected during this study, as well as assessment of INRs feedback regarding the use of software.

The feedback will be collected using the survey and 1-2 interviews with each INR.
Sample size: 100 participants
Cohort: patients undergoing treatment of an intracranial aneurysm with one of the FDs compatible with PreSize Neurovascular software.

Intervention Type
Other

Primary outcome(s)
1. PreSize Neurovascular accuracy at simulating stent length when the software is used in real clinical practice. Accuracy will be assessed by comparing the simulated deployed stent length estimated by PreSize Neurovascular software using pre-operative imaging and the observed deployed stent length from post-operative imaging.

Key secondary outcome(s)
1. Discrepancy in stent devices (make, length, diameter) selected when at the pre-operative planning stage INRs use traditional planning methods versus when they use PreSize Neurovascular
2. INR satisfaction with the software measured using post-procedural short periodic surveys and qualitative interviews with each INR
3. Planning duration when INRs use traditional planning methods versus when they use PreSize Neurovascular software. The planning duration for the two approaches will be recorded in real-time at the pre-operative stage.
4. Procedure duration and radiation dose during the procedure in cases planned with PreSize Neurovascular. Duration will be measured by timestamps in intra-operative imaging and radiation dose will be recorded post-procedure. The same measures will be collected from historical data from past procedures.
5. Intra-operative corrections, defined as devices deployed additionally and discarded as well as

manual manipulations by INRs due to suboptimal stent fit observed in cases planned using PreSize Neurovascular. The corrections will be recorded post-procedure. The same measures will be collected from historical data from past procedures.

Completion date
31/07/2025

Eligibility

Key inclusion criteria
1. Adults aged 18 years or above
2. Indicated to receive treatment for an intracranial aneurysm with one of the FDs compatible with PreSize Neurovascular at one of the participating NHS sites
3. Able to receive both pre-operative 3D rotational angiography (3DRA) and post-operative 2D digital subtraction angiography (2DSA) or cone-beam computed tomography (CT), excluding allergy to iodinated contrast media

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
150 Years

Sex
All

Total final enrolment
103

Key exclusion criteria
1. Any reasons in the opinion of the investigator, e.g. patient cases previously fitted with coiling in the same aneurysmal area might be deemed inappropriate for the purposes of this study if it significantly impacts the contrast in the pre-operative X-ray imaging
2. Unable to give informed consent

Date of first enrolment
04/08/2022

Date of final enrolment
31/07/2024

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
England
LS1 3EX

Study participating centre
St Georges
St. Georges Hospital
117 Suttons Lane
Hornchurch
England
RM12 6RS

Study participating centre
Royal Preston Hospital
Sharoe Green Lane North
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PR2 9HT

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
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Study participating centre
National Hospital for Neurology & Neurosurgery
Queen Square
London
England
WC1N 3BG

Study participating centre
The Walton Centre
Lower Lane
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Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
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G51 4TF

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Study participating centre
Cardiff & Vale University Health Board
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Sponsor information

Organisation
Oxford Heartbeat Ltd

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

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