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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	[X] Prospectively registered [_] Protocol
Registration date 12/05/2022	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 29/05/2025	**Condition category** Circulatory System	[_] 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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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
296470

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50137, IRAS 296470

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

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

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact the R&D office of a participating hospital to request one

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 measure

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.

Secondary outcome measures
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.

Overall study start date
01/06/2020

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

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

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
England

Scotland

United Kingdom

Wales

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

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

Study participating centre

Royal Preston Hospital
Sharoe Green Lane North
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Study participating centre
National Hospital for Neurology & Neurosurgery
Queen Square
London
United Kingdom
WC1N 3BG

Study participating centre
The Walton Centre
Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7LJ

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Queens Hospital
Rom Valley Way

Romford
United Kingdom
RM7 0AG

Study participating centre
Cardiff & Vale University Health Board
Heath Park
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Sponsor information

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Sponsor type
Industry

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

Publication and dissemination plan
Results of the study will also be disseminated via paper submissions to relevant peer-reviewed journals and conferences. The results are intended to be published within 1 year after the study completion. Plain English results and outcomes will also be disseminated in relevant media, in collaboration with Patient and Public Initiative groups.

Intention to publish date
31/07/2025

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