COVER

The impact of COVID-19 pandemic on the provision, practice and outcomes of vascular surgery

PROTOCOL

IRAS number	282224
Sponsor	University Hospitals Coventry & Warwickshire NHS Trust
Sponsor reference	RB485520
Funder	VSGBI & NIHR
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Planned End date	13/04/2020

Protocol Amendments			
Amendment Number	**Protocol Version**	**Date of Amendment**	**Date of Approval**

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research, the ICH Good Clinical Practice guidelines and the Sponsor's SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

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Name (please print):

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Position:

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Chief Investigator:

Signature: Date:

..../...../.....

Name: (please print):

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Position:

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KEY CONTACTS

Chief Investigator	Professor Christopher Imray University Hospitals Coventry & Warwickshire Clifford Bridge Road Coventry CV2 2DX Email: christopher.imray@uhcw.nhs.uk Tel: 02476965264
Co-investigators	Miss Ruth Benson - VERN President University Hospitals Coventry & Warwickshire Clifford Bridge Road Coventry CV2 2DX Email: christopher.imray@uhcw.nhs.uk Tel: 02476965264 Mr Sandip Nandhra NIHR DEC Newcastle Newcastle upon Tyne NE1 7RU Email: sjnandhra@gmail.com Tel: 01912086000 Mr Athanasios Saratzis NIHR Leicester Biomedical Research Centre Glenfield Hospital LE3 9QP Email: as875@le.ac.uk Tel: 01162524785 **The Vascular and Endovascular Research Network Collaborators** www.vascular-research.net Email: vern.arterial.disease@gmail.com *No address or telephone available*
Sponsor & Co-ordination Centre	Ceri Jones Head of Research & Development Research & Development 4th Floor Rotunda University Hospitals Coventry & Warwickshire Clifford Bridge Road Coventry CV2 2DX Email: R&DSponsorship@uhcw.nhs.uk Tel: 02476965031
Funder	NIHR Leicester Cardiovascular Biomedical Research Centre Leicester Glenfield Hospital Groby Road LE39QP Email: as875@le.ac.uk Tel: 01162044768

STUDY SUMMARY

Full title	The impact of COVID-19 pandemic on the provision, practice and outcomes of vascular surgery	
Short title	COVER	
Aim	Assess the impact of COVID-19 on vascular surgery	
Design	Multicentre Cohort Study	
Participants	All patients with a vascular pathology idenfied and treated during the COVID-19 pandemic	
Sample size	200 participants - ESTIMATED	
Planned project period	24 months - ESTIMATED	
	Objectives	**Outcome Measures**
Primary	Assess how the COVID-19 pandemic has changed the provision of vascular services in the UK	Collect data regarding the types of procedures performed in vascular units.
Secondary	Assess how the COVID-19 pandemic has impacted on short and medium term outcomes of vascular patients in the UK	Collect data regarding outcomes after surgery or treatment of any kind at 3, 6, and 12 months.

Key Words: **Coronavirus, Cohort study, Outcomes, Vascular, Surgery**

SCHEDULE OF EVENTS

Table 1: Schedule of Events

The duration of this project will depend on the duration of the COVID19 pandemic

We aim to capture information throughout the pandemic and then for 12 months after the pandemic has ended (i.e. Tier 3 outcomes for 12 months).

Procedure	Screening	Baseline	3 months	6 months	12 months
Eligibility assessment	X	X			
Informed consent (Tier 2 only)		X			
Demographic data (DOB, sex) Stored only locally		X			
Relevant clinical history		X			
Current medications		X			
Assessment of outcomes i.e. death or amputation or stroke		X	X	X	X
End of study		X			X

Contents

LIST OF ABBREVIATIONS

AAA	Abdominal Aortic Aneurysm
AR	Adverse reaction
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
EC	Ethics Committee (see REC)
EVAR	Endovascular Aneurysm Repair
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
IB	Investigators Brochure
ICF	Informed Consent Form
ICH	International Conference of Harmonisation
IMP	Investigational Medicinal Products
ISF	Investigator Site File
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NRES	National Research Ethics Service
OAR	Open Aneurysm Repair
PI	Principal Investigator
PIL/S	Participant/ Patient Information Leaflet/Sheet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SMF	Study Master File
SOP	Standard Operating Procedure
SpR	Surgical Registrar

STUDY PROTOCOL

The impact of COVID-19 pandemic on the provision, practice and outcomes of vascular surgery

1. INTRODUCTION

The COVID-19 pandemic has already had a significant impact on worldwide healthcare systems. There is an urgent need to quantify the specific impact on the provision of vascular and endovascular surgery and the adjustments made to standard vascular practice in light of the pandemic. Reasons for this include:

1. The Vascular Society of Great Britain and Ireland (VSGBI) has released a statement with guidance for altering clinical management of patients with vascular diseases, due to the limitations on healthcare resources and capacity. Worldwide, centres are doing the same as the pandemic has progressed. For most, this involves offering fewer vascular interventions alongside postponing any non-urgent interventions and treatments. Assessing how centres implement the VSGBI recommendations and manage patients in the context of the considerable changes to available resources is imperative during this outbreak and any future major incidents.

2. An international snapshot of how each unit is changing their practice at the patient level in response to the pandemic will ensure that centres across the UK and the world are aware of global practice to unify their planning during the pandemic.

3. The impact of cancelling elective work, deferring all but the most urgent and emergency surgery and proceeding to amputation without complex revascularisation, will be felt almost immediately. However, we must anticipate the volume of work that, after resuming a normal service again, will need to be managed on top of standard case volume. Knowing the impact of the pandemic on the numbers of cases deferred and how their overall care has changed is imperative in order to plan future vascular care both nationally and internationally.

This project is a three-tiered study designed to answer these questions. We aim to capture global data on vascular practice(s) during the pandemic; how this evolves over time; and to understand the impact on outcomes in the short and medium-term.

This project will be led by the **Vascular and Endovascular Research Network (VERN)**. This is an established vascular research collaborative, which has previously designed and delivered several similar projects across the UK and internationally. Details about VERN, including the membership of its executive committee, can be found online: www.vascular-research.net (updated regularly). This project is also formally supported by the VSGBI, the British Society for Endovascular Therapy, and the Rouleaux Club (the UK body representing vascular surgery trainees).

2. RATIONALE

2.1 Aims and hypothesis

This project is a three-tiered study designed to answer the questions covered in the Introduction i.e. assess the impact. We aim to capture global data on vascular practice(s) during the pandemic; how this evolves over time; and to understand the impact on outcomes in the short and medium-term.

2.2 Justification

This project will provide clinicians assessing and treating patients with vascular disease an understanding of the impact of the COVID19 pandemic in order to plan patients' care accordingly in the future and also be prepared for future similar issues.

2.3 Assessment and management of risk

This project will have no impact on patients' journey in the NHS or any other healthcare provider.

3. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1 Primary objective

The main objective of this project is to understand and evaluate the impact of the COVID-19 pandemic on global vascular practice and the effect on outcomes for patients presenting / receiving treatment during the pandemic.

P *Population (patients) – All patients with a vascular pathology.*

I *Intervention – NONE. Observational study.*

C *Comparison group – NONE. Observational study.*

O *Outcome of interest – Tier 1: state of vascular services per centre weekly; Tier 2: procedures performed in each centre; Tier 3: assessment of longer-term outcomes.*

T *Time – end of study 12 months after the end of the COVID19 pandemic.*

Details regarding all endpoints are listed under STUDY PROCEDURES under each Tier of this project.

4. STUDY DESIGN

Three tiered project.

Tier 1 does not constitute research (remote anonymised survey of healthcare professionals)

Tier 2 and **3** constitute research and are described in full detail under STUDY PROCEDURES (see below). These are observational studies within.

5. STUDY SETTING

This is a multicentre observational study in NHS sites across the UK, including England, Scotland, and Wales.

All NHS sites which provide regular care to vascular patients are eligible (secondary care).

This study will have NO impact on regular NHS care and will only documents patients' NHS care pathways.

6. ELIGIBILITY CRITERIA

All patients with vascular diseases are eligible to take part, as long as they have received assessment or treatment for a vascular problem in an NHS secondary care vascular unit.

6.1 Inclusion criteria

Vascular pathology including: aneurysmal disease, stroke, peripheral arterial disease, venous disease.

6.1 Exclusion criteria

Only adult patients will be eligible to consent (tier 2 only) and take part.

7. STUDY PROCEDURES

This project will consist of THREE stages ("TIERS").

Tier 1 is an online survey of experts in vascular care (anonymised) and does not constitute research. Consent for this is not necessary.

Patients (for Tiers 2 and 3) will be identified prospectively:

At the time of surgery

At the time of referral to the vascular on-call team.

These constitute research.

Tier 1 - Changes to vascular unit level clinical processes

Primary objective

To objectively capture the changes made to the structure and delivery of vascular surgery at unit level throughout the COVID-19 pandemic, and compare it to the guidance provided by the VSGBI as well as other national/international committees (e.g. the Society for Vascular Surgery, the European Society for Vascular Surgery).

Methods

The Tier 1 "service evaluation study" will be circulated to all interested centres and data collected (remotely/online) at the start of COVER. The aim is to identify changes to the routine or standard vascular service structure. This will be conducted at roll-out and upon each centre registering to participate in the overall study bundle. This survey will be repeated at regular intervals to document ongoing changes, in response to the changing circumstances. These intervals will vary depending on how the pandemic progresses internationally. Collaborators will be updated at least once weekly. It is expected that the responses will reflect the unit practice as a whole and should therefore be a unified unit level response approved by the centre or centre lead.

Outcomes

Primary outcome:

To document changes to structure and processes within the vascular service, including:

- Operations offered/not offered
- Thresholds for offering admission/intervention
- Seniority and/or number of specialists performing caseload
- Management of screening programmes
- Imaging availability
- Interventional radiology support and availability
- Conduct of multi-disciplinary meetings
- Changes to trainee and consultant rotas

- Surgeons' commitments and clinic availability
- Use of the vascular team members to cross cover other specialties

This information will be fed back to the VSGBI (and other relevant bodies) to allow real-time feedback on practicalities of the new guidelines. This could support adaptations needed to support best practice for patients and surgeons as the situation progresses.

Tier 2 – Vascular and endovascular procedural data capture

Primary objective

This tier of the project is aimed at capturing data on all vascular and endovascular interventions being undertaken throughout the COVID-19 pandemic. It is anticipated that the type and nature of vascular procedures performed will change due to the pressures on the wider healthcare service and rationing of resources or in-patient beds.

Methods

This will be undertaken for a 3 month period in the first instance. These time periods are subject to change depending on how the pandemic progresses.

Outcomes

Primary outcome:

To document all vascular surgery and interventional procedures performed throughout the COVID-19 pandemic across participating centres; during this stage we will only collect the name of the procedure performed, time and date, with intra-operative details; no patient-specific information will be collected as part of this.

Specifically, we will collect the following information using a remote purpose built data collection form (per centre/patient):

- Type of procedure performed
- Time taken from presentation to the surgical team to intervention
- Mode of referral (primary vs. secondary care)
- Site of surgery – hub or spoke hospital
- Imaging modalities used and timings
- Emergency classification i.e. urgent/emergency/elective
- Operative technique(s) and device(s) used
- Mode(s) of anaesthesia (local, regional, general, locoregional, other)
- Whether suspected or confirmed COVID-19 positive (+ve) at time of surgery, COVID-19 +ve after surgery, or COVID-19 negative (-ve)

- Documentation of changes to usual practice for this specific procedure as per surgeon's standard protocol (type of procedure, type of anaesthetic, post-procedural destination)

These **secondary outcomes** will be collected after surgery has been performed at 3, 6, and 12 months:

- Re-admission
- Re-intervention
- All-cause mortality
- Operation-specific morbidity
- Morbidity
- [If COVID-19 +ve] - respiratory outcome, admission to intensive care unit.

Each centre will assign a unique patient-specific and study-specific number to each procedure/patient (kept in local site files in the NHS institutions) and then this information will be collected locally three and six months after surgery has taken place. This will be uploaded anonymised on the data collection tool.

Tier 3 – Changes to acute vascular care management

Primary objective

To identify how the management of all referred urgent vascular cases changes throughout the COVID-19 pandemic. This is to identify the many anticipated deviations from pre-pandemic best practice or pre-defined standards for acute/urgent cases due to healthcare pressures. This will focus on chronic limb-threatening ischaemia, symptomatic carotid disease, acute aortic syndromes and aneurysmal disease.

Methods

This will take place over a minimum of one month and will invite vascular specialists to complete an anonymised proforma for every patient with any of the conditions listed above, referred to the vascular service. Timings might change based on the duration of the pandemic.

Outcomes

Primary outcome:

To document any deviation from "best vascular practice" and the impact on patient care, specifically focussing on:

Chronic Limb Threatening Ischaemia (CLTI):

- Decision to discharge / admit / refer to hot clinic
- Decision for endovascular or open surgery first
- Decision for best medical therapy or palliation or primary amputation

Symptomatic carotid disease

- Number of patients managed with best medical therapy (BMT)
- Modifications to the indication and decision for carotid endarterectomy (CEA)
- Delays to treatment due to lack of theatre/bed availability

Abdominal Aortic Aneurysm (AAA)

- Increasing use of Endovascular repair (if applicable)
- Changes to criteria for intervention
- Decisions for palliation, i.e. 'turn down'

Acute Aortic syndrome (AAS)

- Decision to manage in non-critical care beds
- Changes to imaging protocol at unit level
- Decision to defer surgery

Secondary Outcomes:

To collect longitudinal data to identify condition-specific outcomes for these patients at 3, 6 months and 1 year.

- Example condition specific outcome measures to include:
- CLTI - limb salvage, amputation free survival, all-cause mortality
- Carotid disease - ipsilateral stroke rate, any stroke rate, all-cause mortality
- AAA - aneurysm-related mortality, all-cause mortality
- AAS - complication rate including ruptures, all-cause mortality.

7.1 Recruitment

In UK centres, patients will be recruited by a GCP trained VERN doctor or nurse in each vascular centre and then consented as per GCP guidance. A written informed consent form for tier 2 will be kept at each site file locally.

Anonymised information on participants will be collected using a remote case report form.

7.1.1 Patient identification

Patients will be identified daily via conversation with the on call registrar and consultant for vascular surgery.

7.1.2 Screening

All patients will be adults. If they are being recruited into tier 2, they must be able to provide written informed consent. Patients who cannot read or write or have cognitive impairment will not be included.

7.1.3 Payment

No payments will be made to participants.

7.2 Consent (Tier 2)

This is required for tier 2 only. Participants will be approached by the local VERN and COVER investigator to provide written informed consent. The Principal Investigator (PI) retains overall responsibility for the conduct of research at their site; this includes the taking of informed consent of

participants at their site. They must ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained and competent.

Informed consent will be obtained prior to the participant having any data recorded in Tier 2. The right of a participant to refuse participation without giving reasons will be respected.

The participant will be free to withdraw at any time from the study without giving reasons and without prejudicing his/her further treatment and will be provided with a contact point where he/she may obtain further information about the study. Data collected up to the point of withdrawal will only be used after withdrawal if the participant has consented for this. Where a participant is required to re-consent or new information is required to be provided to a participant it is the responsibility of the PI to ensure this is done in a timely manner.

Patients who cannot read or write or have cognitive impairment will not be included. Participants will be given a PIS prior to signing a consent form and will have the opportunity to ask questions.

A capable person will:

1. understand the purpose and nature of the research
2. understand what the research involves, its benefits (or lack of benefits), risks and burdens
3. understand the alternatives to taking part
4. be able to retain the information long enough to make an effective decision
5. be able to make a free choice
6. be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity).

7.3 Storage and analysis of samples

No samples will be stored or analysed.

7.4 End of study definition

12 months after the inclusion of the last patient i.e. 12 months after the last recruited patient has taken part.

8. STATISTICS AND DATA ANALYSIS

8.1 Sample size calculation

This is an observational study and given the unique nature of this unforeseen pandemic we cannot perform sample size calculations.

8.2 Planned recruitment rate

We expect one to five participants per centre per week.

8.3 Statistical analysis plan

We will report absolute numbers of patients having each procedure during this observational study period. We will report proportion of patients dying or having amputation at 3, 6, and 12 months. No comparisons will be made.

8.4 Procedure(s) to account for missing or spurious data

In the event of missing data, the study co-ordinator and chief investigator will contact the investigator collecting data. Missing data will be minimised by careful data management. Missing data will be described with reasons given where available; the number and percentage of individuals in the missing category will be presented. All data collected on data collection forms will be used, since only essential data items will be collected. No data will be considered spurious in the analysis since all data will be checked and cleaned before analysis.

9. DATA MANAGEMENT

9.1 Data collection tools and source document identification

All data will be collected prospectively using a purpose built electronic database, using the REDCap platform, which is overseen by the University of Birmingham (main contact: Miss Ruth Benson). Data will be collected and uploaded by senior surgical trainees with appropriate research and REDCap training, from the VERN collaborative, for both Tiers 2 and 3.

9.2 Data handling and record keeping

A specific study number will be assigned to each patient to allow anonymised data to be collected using a purpose built REDCap platform that will be accessible at each centre.

The CRFs will be completed by the investigators at each site, aiming to complete data collection within one day after the patient has been discharged home. Data will be entered onto the REDCap web platform, which will be purpose built for

this study using secure NHS servers and procedures which have been tested, validated and are widely used for NHS research of this nature. Investigators will receive relevant training at the site initiation visits. The participants will be identified by a study specific participant's number and/or code in any database. The name and any other identifying detail will not be included in any study data electronic file. The patient's name will be visible on their consent form which will be stored in an NHS institution at each study site as per NHS and GCP guidance. Each patient will be assigned their unique identifying number once recruited and if applicable, this will be linked to their consent form at the originating site. No further patient details will be shared on REDCap or between centres. Patients' names, date of birth, address or any other identifier (including contact details) will not be shared on REDCap.

9.3 Source data and access to data

Source documents are original documents, data, and records from which participants' CRF data are obtained. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarised into the CRF), clinical and office charts, laboratory and pharmacy records, diaries, microfiches, radiographs, and correspondence. CRF entries will be considered source data if the CRF is the site of the original recording (e.g. there is no other written or electronic record of data). All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number, not by name. The persons designated to collect data for this study may collect data using a printed CRF anonymously (using only the study identification number and no other patient identifiable data) but are required to input the data on the electronic data collection software (REDCap) within the space of 24 hours (1 calendar day).

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit monitoring, audits and inspections.

The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by initials and a participants ID number on the CRF and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so.

9.4 Archiving

Following the resolution of queries and confirmation of study close-out by the Chief Investigator, all essential documentation will transferred to a third party archiving service, which provides suitable fire and water-resistant facilities. Study files will be archived for a period of 25 years. Access to the study

documentation will be restricted to named individuals within the study team with express permission from the Chief Investigator.

10. TRIAL OVERSIGHT

10.1 Role and responsibilities of the Sponsor

UHCW has agreed to act as sponsor for this trial and will undertake the responsibilities of sponsor as defined by the UK Policy Framework for Health and Social Care Research and ICH Good Clinical Practice. An authorised representative of the Sponsor has approved the final version of this protocol with respect to the trial design, conduct, data analysis and interpretation and plans for publication and dissemination of results. As sponsor, UHCW provides indemnity for this study and, as such, will be responsible for claims for any negligent harm suffered by anyone as a result of participating in this study. The indemnity is renewed on an annual basis and will continue for the duration of this study.

10.2 Role and responsibilities of the Funder

Funding for this study is provided by Vascular Society of Great Britain and Ireland. The NIHR funds the salary of Mr Saratzis – co-CI.

10.3 Trial Management Arrangements

This study will be managed by the Vascular and Endovascular Research Network (VERN) with monthly remote teleconferencing calls with the CI and research team i.e. Miss Benson, Mr Nandhra, and Mr Saratzis.

Study Co-ordinator / Manager:

Miss Benson i.e. The Study Co-ordinator / Manager will have responsibility for overseeing day to day coordination of the study. The relevant responsibilities include but are not limited to:

- Coordinating protocol development, patient and management documents
- Correspondence with study funders
- Setting up and maintaining the Master File
- Ensuring necessary approvals are in place before the start of the trial at each site
- Providing training to personnel
- Providing data management support; including data input, maintenance of the trial database and raising of queries
- Producing progress reports and coordinating TSC meetings and minutes
- Ensuring data security and quality and ensuring data protection laws are adhered to
- Ensuring complete records are in place for audit and monitoring purposes

- Ensuring the study is conducted in accordance with the ICH GCP
- Archiving all original documents including the data forms in line with UHCW NHS Trust policy.

10.3.1 Principal Investigators

"Site Principal Investigator responsibilities include, but are not limited to:

- Ensuring that the study is conducted as set out in the protocol and supporting documents
- Delegating study related responsibilities only to suitably trained and qualified personnel and ensuring that those with delegated responsibilities fully understand and agree to the duties being delegated to them
- Ensuring that CVs and evidence of appropriate training for all Site staff are available in the Site File
- Ensuring that all delegated duties are captured in the Delegation Log
- Ensuring all Adverse Events are documented and reported promptly to the Manager
- Ensuring the study is conducted in accordance with ICH GCP principles
- Allowing access to source data for monitoring, audit and inspection
- Ensuring that all source data is complete and provided to the Manager at regular intervals.

11. MONITORING, AUDIT & INSPECTION

The study may be monitored by the Research & Development Department at UHCW as representatives of the Sponsor, to ensure that the study is being conducted as per protocol, adhering to Research Governance and GCP. The approach to, and extent of, monitoring may be specified in a monitoring plan determined by the risk assessment undertaken prior to the start of the study.

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1 Ethical approval and research governance

The study will be conducted in compliance with the principles of the ICH GCP guidelines and in accordance with all applicable regulatory guidance, including, but not limited to, the UK policy framework for health and social care research. Ethical approval for this study will be sought from the Research Ethics Committee combined with Health Research Authority (HRA) approval. No study activities will commence until favourable ethical opinion and HRA approval has been obtained. Progress reports and a final report at the conclusion of the trial will be submitted to the approving REC within the timelines defined by the

committee. Confirmation of capacity and capability will be obtained from the R&D department prior to commencement of the study at all participating sites.

Successful ethical approval for the UK was granted on the 2nd of April 2020 (Rec Reference: 20/NW/0196 Liverpool Central) for study Tiers 2 and 3. HRA approval was granted on the 3rd of April 2020. The approval mandates patient consent for tier 2 in order to capture procedural data and follow-up. Tier 3 was deemed not to require specific consent from the participant as often these are based on referred information and there is likely to be no direct patient contact.

12.2 **Peer review**

The study has been reviewed by all VERN members (12 executive committee members), including nurses and doctors.

12.3 **Public and Patient Involvement**

The study has been discussed with a patient via the VERN executive committee, who has approved the design and conduct.

12.4 **Data protection and patient confidentiality**

The study will comply with the current Data Protection regulations and regular checks and monitoring will be undertaken by the Trial Manger to ensure compliance. Participants will be assigned a unique identifier upon enrolment in to the study to allow pseudonymisation of patient-identifiable data. Access to patient identifiable data will be restricted to members of the study co-ordination team who require it for the performance of their role. Electronic data will be stored on password protected encrypted drives and hard copies of study documents will be stored in locked filing cabinets in secure entry-card protected sites.

13. DISSEMINATION POLICY

Findings will be emailed to the Vascular Society of Great Britain and Ireland and the National Vascular Registry will be informed. Finally, an abstract will be submitted for presentation at the annual VSGBI Conference.

Collaborators from each site who contribute patients will be recognised on any resulting publications as PubMed-citable co-authors. The VERN model for collaborative authorship that will be used for any outputs arising from this project can be found here: https://vascular-research.net/authorship-policy/.

An example of this can be found here:
https://pubmed.ncbi.nlm.nih.gov/29452941.