ISRCTN80453162 https://doi.org/10.1186/ISRCTN80453162

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

Submission date
12/04/2020

Recruitment status
No longer recruiting

Registration date
14/04/2020

Overall study status
Completed

Last Edited
10/03/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
The COVER study is an international study aiming to assess how the COVID-19 coronavirus pandemic has changed the medical care of patients who have artery and vein problems. It consists of three separate projects or "Tiers". The 1st Tier is an internet based survey where doctors and healthcare professionals are asked some questions (every week) about how the care of these patients has changed. The 2nd Tier is a study where each hospital inputs the nature of the surgeries performed every week on an online database. The 3rd Tier is similar to the 2nd Tier; it will collect information on what happens to patients having artery or vein surgery during the pandemic. Finally, we will collect information regarding what happened to these patients for a year.

This study will help healthcare professionals understand how the COVID-19 pandemic has changed the care of patients with artery and vein problems. This is an important question, as patients with such health problems typically have many other health issues and/or are elderly. This makes them it more likely for them to develop COVID-19 related problems and life threatening complications.

Who can participate?
Any patient with a vascular condition.

What does the study involve?
Health professionals at participating centres will complete an online survey regarding vascular surgery that has been carried out.

What are the possible benefits and risks of participating?
None.

Where is the study run from?
University Hospital Coventry and Warwickshire (UK)

When is the study starting and how long is it expected to run for?
April 2020 to April 2022

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

Who is the main contact?
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Study website
http://vascular-research.net/projects/cover-study-covid-19-vascular-service-study/

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
282224

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
COVER_01, IRAS 282224

Study information

Scientific Title
The impact of the COVID-19 pandemic on the provision, practice, and outcomes of vascular surgery. An international cohort study (COVER)

Acronym
COVER

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 02/04/2020, Liverpool Central NHS Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8056; liverpoolcentral.rec@hra.nhs.uk), ref: 20/NW/0196

Study design
Observational longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Available for download (alongside all documents) at the study website.

Health condition(s) or problem(s) studied
Any vascular condition, including: aortic or other type of aneurysmal disease, peripheral arterial disease, venous disease, vascular malformations, trauma, major haemorrhage, access (for renal dialysis), carotid (and cerebrovascular) disease, any other type of pathology treated by vascular surgeons.

Interventions
This project is a three-tiered study designed to fully elucidate the impact of the COVID-19 pandemic on vascular surgery across the world.

The aim of Tier 1 is to document how the provision and availability of vascular services evolves over time per unit/region/country.

The aim of Tier 2 is to prospectively capture data on all vascular procedures performed during the pandemic and understand the impact on outcomes in the short and medium-term (up to 1 year).

The aim of Tier 3 is to document (prospectively) deviations from standards of care/practice during the pandemic in vascular patients.

The main objective of the COVER study 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.
Population (patients) – All patients with a vascular pathology.
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.
Time – end of study 12 months after the end of the COVID19 pandemic.

The study is formally supported by the Vascular Society of Great Britain and Ireland (VSGBI), the British Society for Endovascular Therapy (BSET), the Rouleaux Club, the NIHR, SingVasc and several national vascular surgery societies in Europe, Asia, Australia, New Zealand, and the Americas.

Intervention Type
Other

Primary outcome measure
1. Structure and processes within the vascular service measured using a novel online questionnaire weekly until the end of data collection
2. Document all vascular surgery and interventional procedures performed using an online purpose-built data collection tool (per centre/patient) at baseline, time/date of surgery, date of discharge from hospital, three, six, and twelve months:
2.1. Type of procedure performed
2.2. Time taken from presentation to the surgical team to intervention
2.3. Mode of referral (primary vs. secondary care)
2.4. Site of surgery – hub or spoke hospital
2.5. Imaging modalities used and timings
2.6. Emergency classification i.e. urgent/emergency/elective
2.7. Operative technique(s) and device(s) used
2.8. Mode(s) of anaesthesia (local, regional, general, locoregional, other)
2.9. Whether suspected or confirmed COVID-19 positive (+ve) at time of surgery, COVID-19 +ve after surgery, or COVID-19 negative (-ve)
2.10. 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)
3. Management of all referred urgent vascular cases using the online survey, focusing on:
3.1. Chronic Limb Threatening Ischaemia (CLTI):
3.1.1. Decision to discharge/admit/refer to a "hot"/emergency clinic
3.1.2. Decision for endovascular or open surgery first
3.1.3. Decision for best medical therapy or palliation or primary amputation
3.2. Carotid disease:
3.2.1. Number of patients managed with best medical therapy (BMT)
3.2.2. Modifications to the indication and decision for carotid endarterectomy (CEA)
3.2.3. Delays to treatment due to lack of theatre/bed availability
3.3. Abdominal Aortic Aneurysm (AAA)
3.3.1. Increasing use of Endovascular repair (if applicable)
3.3.2. Changes to criteria for intervention
3.3.3. Decisions for palliation, i.e. 'turn down'
3.4. Acute Aortic syndrome (AAS)
3.4.1. Decision to manage in non-critical care beds
3.4.2. Changes to imaging protocol at unit level
3.4.3. Decision to defer surgery

Secondary outcome measures
1. Collected after surgery has been performed at three, six, and twelve months using patient records:
1.1. Re-admission
1.2. Re-intervention
1.3. All-cause mortality
1.4. Operation-specific morbidity

1.5. Morbidity
1.6. [If COVID-19 +ve] - respiratory outcome, admission to intensive care unit
2. Condition-specific outcomes at 3, 6 months and 1 year:
2.1. CLTI - limb salvage, amputation free survival, all-cause mortality
2.2. Carotid disease - ipsilateral stroke rate, any stroke rate, all-cause mortality
2.3. AAA - aneurysm-related mortality, all-cause mortality
2.4. AAS - complication rate including ruptures, all-cause mortality

Overall study start date
23/03/2020

Completion date
01/04/2022

Eligibility

Key inclusion criteria
Any patient with a vascular condition

Participant type(s)
All

Age group
All

Sex
Both

Target number of participants
20 centres, 10 patients from each centre

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
09/04/2020

Date of final enrolment
01/04/2022

Locations

Countries of recruitment
Afghanistan

Albania

Algeria

American Samoa

Andorra

Angola

Anguilla

Antarctica

Antigua and Barbuda

Argentina

Armenia

Aruba

Australia

Austria

Azerbaijan

Bahamas

Bahrain

Bangladesh

Barbados

Belarus

Belgium

Belize

Benin

Bermuda

Bhutan

Bolivia

Bonaire Saint Eustatius and Saba

Bosnia and Herzegovina

Botswana

Bouvet Island

Brazil

British Indian Ocean Territory

Brunei Darussalam

Bulgaria

Burkina Faso

Burundi

Cabo Verde

Cambodia

Cameroon

Canada

Cayman Islands

Central African Republic

Chad

Chile

China

Christmas Island

Cocos (Keeling) Islands

Colombia

Comoros

Congo

Congo, Democratic Republic

Cook Islands

Costa Rica

Croatia

Cuba

Curaçao

Cyprus

Czech Republic

Côte d'Ivoire

Denmark

Djibouti

Dominica

Dominican Republic

Ecuador

Egypt

El Salvador

England

Equatorial Guinea

Eritrea

Estonia

Eswatini

Ethiopia

Falkland Islands

Faroe Islands

Fiji

Finland

France

French Guiana

French Polynesia

French Southern Territories

Gabon

Gambia

Georgia

Germany

Ghana

Gibraltar

Greece

Greenland

Grenada

Guadeloupe

Guam

Guatemala

Guernsey

Guinea

Guinea-Bissau

Guyana

Haiti

Heard Island and McDonald Islands

Holy See (Vatican City State)

Honduras

Hong Kong

Hungary

Iceland

India

Indonesia

Iran

Iraq

Ireland

Isle of Man

Israel

Italy

Jamaica

Japan

Jersey

Jordan

Kazakhstan

Kenya

Kiribati

Korea, North

Korea, South

Kosovo

Kuwait

Kyrgyzstan

Lao People's Democratic Republic

Latvia

Lebanon

Lesotho

Liberia

Libya

Liechtenstein

Lithuania

Luxembourg

Macao

Madagascar

Malawi

Malaysia

Maldives

Mali

Malta

Marshall Islands

Martinique

Mauritania

Mauritius

Mayotte

Mexico

Micronesia, Federated States of

Moldova

Monaco

Mongolia

Montenegro

Montserrat

Morocco

Mozambique

Myanmar

Namibia

Nauru

Nepal

Netherlands

Netherlands Antilles

New Caledonia

New Zealand

Nicaragua

Niger

Nigeria

Niue

Norfolk Island

North Macedonia

Northern Mariana Islands

Norway

Oman

Pakistan

Palau

Palestine, State of

Panama

Papua New Guinea

Paraguay

Peru

Philippines

Pitcairn

Poland

Portugal

Puerto Rico

Qatar

Romania

Russian Federation

Rwanda

Réunion

Saint Barthélemy

Saint Helena, Ascension and Tristan da Cunha

Saint Kitts and Nevis

Saint Lucia

Saint Martin (French part)

Saint Pierre and Miquelon

Saint Vincent and the Grenadines

Samoa

San Marino

Sao Tome and Principe

Saudi Arabia

Senegal

Serbia

Seychelles

Sierra Leone

Singapore

Sint Maarten (Dutch part)

Slovakia

Slovenia

Solomon Islands

Somalia

South Africa

South Georgia and the South Sandwich Islands

South Sudan

Spain

Sri Lanka

Sudan

Suriname

Svalbard and Jan Mayen

Sweden

Switzerland

Syria

Taiwan

Tajikistan

Tanzania

Thailand

Timor-Leste

Togo

Tokelau

Tonga

Trinidad and Tobago

Tunisia

Turkmenistan

Turks and Caicos Islands

Tuvalu

Türkiye

Uganda

Ukraine

United Arab Emirates

United Kingdom

United States Minor Outlying Islands

United States of America

Uruguay

Uzbekistan

Vanuatu

Venezuela

Viet Nam

Virgin Islands, British

Virgin Islands, U.S.

Wallis and Futuna

Western Sahara

Yemen

Zambia

Zimbabwe

Study participating centre
University Hospital Coventry and Warwickshire (lead Research and Development centre)
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Sponsor information

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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/025n38288

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
Planned publication in a high-impact peer-reviewed journal.

This is an international effort led by the Vascular and Endovascular Research Network (VERN). The COVER study follows a collaborative authorship policy. All collaborators, including nurses, students, trainees, doctors, and other healthcare professionals, can be eligible for authorship. You can access the authorship policy here: http://vascular-research.net/authorship-policy/

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan

Not provided at registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	Presented at National Research Collaborative Meeting Conference 2020	08/04/2021	06/12/2021	No	No
Protocol article		30/12/2020	06/12/2021	Yes	No
Results article		01/04/2021	06/12/2021	Yes	No
Results article		01/10/2020	06/12/2021	Yes	No
Results article	Qualitative results of clinician survey	03/12/2021	06/12/2021	Yes	No
HRA research summary			28/06/2023	No	No