ISRCTN13202085 https://doi.org/10.1186/ISRCTN13202085

Assessing a healthcare bundle designed to improve the management of patients with artery disease. The CHABLIS Study

Submission date 21/01/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/01/2021	**Overall study status** Completed	
Last Edited 09/04/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and Study Aims
Peripheral Arterial Disease (commonly referred to as PAD) is the commonest cause of amputation and a leading cause of heart problems. More than half of people found to have PAD are expected to die, have an amputation, a stroke or heart attack within five years. Many of the PAD risk-factors, such as smoking, high blood pressure, high cholesterol, high blood-sugars, can be changed when someone has the right medical care. Current doctors' guidelines for the NHS sets clear targets regarding how these risk-factors should be addressed if someone has PAD. Unfortunately, these guidelines are usually not followed in the NHS. To change this, we developed a bundle of checklists and letters called "LEGS" with the help of patients and experts. LEGS is meant to support patients with PAD, GPs, and hospital doctors manage the common PAD risk factors. This might help prevent amputations and other health problems in these patients.

The aim of this study is to test how well the LEGS intervention can be used in real life at three NHS hospitals across England. With the help of patient and healthcare professional interviews (held remotely if necessary due to COVID-19), and a conference when the study finishes (remotely if necessary), there will be the opportunity to make any changes to the intervention before it is adopted across the NHS.

Who can participate?
Adult patients with symptomatic PAD (i.e. intermittent claudication, ischaemic rest pain, or chronic limb threatening ischaemia) referred to secondary care either in a clinic, or for inpatient treatment.

What does the study involve?
Patient Involvement:
Once a patient provides informed consent, we will then use the LEGS bundle of letters and checklists from the first day they receive care for their PAD in hospital. This includes clinic(s) appointments and/or an inpatient stay. Doctors providing their care will use our checklist of the common things that patients with PAD should be offered in terms of medications and/or tests.

All of these suggestions are already part of what is standard NHS care for PAD. Using the patients' medical notes, we will record blood pressure, current medications, medical history, previous surgeries, imaging results, routine blood test results (cholesterol, lipid profile, full blood count), smoking status, and demographic information (age, height, weight, gender). This is all standard information that the NHS already collects. Patients will be given a leaflet which will provide information about PAD and other things they can do to help reduce associated risks.

After patients are discharged from either clinic, or their first patient admission, we will contact them by phone to fill in a questionnaire commonly used to assess people's quality of life. Also, we will make an appointment to see them again in six months after we have used the LEGS bundle checklist and letters to check their legs and overall health. This is standard for someone with PAD. We will again record patients' blood pressure, current medications, medical history, previous surgeries, imaging results, routine blood test results (cholesterol, lipid profile, full blood count), smoking status, and demographic information (age, height, weight, gender). During that appointment we will ask them to fill in a questionnaire which assesses how well people are taking their prescribed medication, called the MARS questionnaire. In addition, patient's GPs will be contacted in order to review prescriptions and medical history to ensure that they received the LEGS bundle documents as intended. We will then record how many times the LEGS bundle was used correctly.

As part of this study patients will also have the option of participating in an interview with a researcher. This will take up to two hours and will be perfomed either remotely, or face-to-face depending upon the patients' preference. In this interview patients will be asked how they found the management of their PAD at hospital and in their GP practice, what their thoughts are of the information leaflet, and if they think it has been of any benefit or not.

Healthcare professionals:
We will invite healthcare professionals who provide care to patients with have symptomatic peripheral arterial disease to attend an interview. During this, we will explore their experiences of delivering the intervention. This will help us evaluate the ability/feasibility of staff in delivering the intervention, overall impression, validity, usability, acceptability and engagement with the intervention. It will include barriers to engagement or delivery and ideas for improving the intervention.

Consensus conference:
We will invite all patients and healthcare professionals who took part in the interviews to attend a consensus conference. The conference will help us decide how to adapt the elements of the LEGS bundle (if necessary) and how to proceed with future large-scale studies.

What are the possible risks and benefits of participating?
If the study is successful, this may benefit thousands of patients across the UK and may prevent hundreds of admissions and deaths every year. It could bring significant cost savings to the NHS as the treatment of these health problems is very expensive. There are no risks.

Where is the study run from?
University of Leicester (UK)

When is the starting and how long will it run for?
February 2020 to June 2022

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

Who is the main contact?
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Integrated Research Application System (IRAS)
289220

Protocol serial number
0749

Study information

Scientific Title
A Community and Hospital cAre Bundle to improve the medical treatment of cLaudIcation and critical limb iSchaemia. The CHABLIS study

Acronym
CHABLIS

Study objectives
Peripheral arterial disease (PAD) happens when the arteries supplying blood to the legs become narrowed or blocked. Patients with PAD may lose their leg, develop heart-attacks or strokes, or die early. Smoking, diabetes, high blood-pressure and cholesterol increase the chances of having PAD. Current NHS guidelines state that patients with PAD should be offered blood-thinners, blood-pressure, and cholesterol tablets. They should also be supported to manage their diabetes better, stop smoking, and exercise more. Our research has shown that very few patients receive this care. This leads to unnecessary deaths and amputations. When we asked patients with PAD how their NHS care could be improved, they said not enough information about PAD treatments was given. They also did not understand the high risk of heart attacks, strokes, and amputations that comes with PAD. Finally, their prescriptions were often wrong. Hospital doctors, GPs and nurses felt communication between doctors should be improved. Based on this information, we developed a bundle of doctors checklists and patients leaflets to help patients with PAD get the right treatment. We called this “LEGS” (LEaflet Gp letter Structured bundle). We are now going to assess whether LEGS can be used in NHS hospitals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/12/2020, Wales National Health Service (NHS) Review Ethics Committee (REC) 7 (Public Health Wales, Building 1, Jobswell Road, St David's Park, SA31 3HB, UK; +44 (0) 1267234567; sasha.barrate@wales.nhs.uk), ref: 20/WA/0319

Study design
Prospective feasibility multicentre cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peripheral arterial disease

Interventions
The intervention used in this research is called "LEGS". It was developed by patients and experts in peripheral arterial disease. It addresses the five key treatment areas (i.e. best medical therapy) identified in our review of best available evidence and clinical guidelines, including National Institute for Health and Care Excellence (NICE) guidance:
i) Lipid control
ii) Antiplatelet therapy
iii) BP control
iv) Smoking cessation
v) Blood-glucose control.

The aim is to improve the medical care of patients with peripheral arterial disease by using the LEGS intervention.

The final LEGS intervention consists of:
i) Inpatient doctors' checklist
One-page checklist developed with the help of Foundation Doctors, Core Surgery and Vascular Trainees, Vascular Surgery and Interventional Radiology Consultants, for patients admitted in a hospital setting. The list is filled initially with the first patient clerking (on admission) by the relevant doctor and then immediately before discharge (last day of inpatient stay).
ii) Outpatient doctors' checklist
One-page checklist for those seen in a clinic. It has been developed with the help of two NHS Vascular Clinic Co-ordinators, a GP, Specialist Vascular Nurses, and Vascular Surgery Consultants. The list is filled in during the outpatient consultation, prompting the doctor or nurse to address all BMT key areas.
iii) LEGS leaflet for patients and relatives (both inpatients and outpatients)
A concise leaflet with information aiming to support patients to achieve their medical care targets. We used the British Heart Foundation and Circulation Foundation PAD documents as a basis, on which the patients' helping us with the development pathway expanded as per their perceptions/preferences. The leaflet covers (in lay language) the implications of a diagnosis of PAD and the key treatment targets of NICE guidance. This is given to the patient upon the diagnosis of symptomatic PAD in the form of severe intermittent claudication or chronic limb threatening ischaemia either during their inpatient stay or at the outpatient consultation. The leaflet is also mailed to the GP and Practice Nurse. It is available in five languages.

iv) LEGS GP letter
A standardised letter with specific action points that cover the main aspects of Best Medical Therapy for PAD. This document was developed by GPs in eleven different regions in England. The letter will be sent to the patient's GP immediately after discharge from hospital (inpatients) or after each clinic visit (outpatient). Specific action points are suggested to the GP and Practice Nurse. The letter addresses the poor and occasionally confusing structure of secondary care communications. It will help support primary care in providing more streamlined Best Medical Therapy for those with PAD.
v) LEGS GP follow-up letter
A follow-up letter will be sent automatically to the GP four weeks after each contact with secondary care (discharge from inpatient stay or visit to the clinic), again prompting action for NICE treatment targets.

Follow-up is 6 months.

Intervention Type
Behavioural

Primary outcome(s)
Number of elements of the LEGS intervention delivered successfully by the clinical team measured using patient records at day of discharge/day of clinic appointment and 15 days later

Key secondary outcome(s))
1. Has the participant been made aware of the diagnosis of peripheral arterial disease and whether relevant medications have been prescribed? (yes/no) by contacting the primary care surgery at day 15
2. Patient medication history from day 0 to 6 months, measured using patient records
3. Health events from day 0 to 6 months, measured using patient records
4. Quality of life measured using the EuroQol-5D (EQ-5D) questionnaire at 6 months

Completion date
04/06/2022

Eligibility

Key inclusion criteria
Patients:
1. Adult (>18 years of age) patient with incapacitating intermittent claudication or chronic limb threatening ischaemia (Rutherford stages 3–6)
2. Referred to secondary care, either in a clinic or for inpatient treatment
3. Willing and able to give written informed consent for participation in the study
4. Access to a telephone or computer with internet access (for those taking part in remote interviews/consensus meeting)

Healthcare professionals:
5. Healthcare professionals who provide care to patients with have symptomatic peripheral arterial disease

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Female participants who are pregnant, lactating or planning a pregnancy during the course of the study
2. Patients who do not have the capacity to consent for themselves
3. Patients with a life-limiting condition whereby conservative management is most appropriate
4. Patients with asymptomatic peripheral arterial disease

Date of first enrolment
01/05/2021

Date of final enrolment
30/10/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Glenfield Hospital
University Hospitals of Leicester NHS Trust
Groby Road
Leicester
United Kingdom
LE3 9QP

Study participating centre
St Thomas' Hopsital
Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Road

London
United Kingdom
SE1 7EH

Study participating centre
Walsgrave General Hospital
University Hospitals Coventry and Warwickshire NHS Trust
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CV2 2DX

Study participating centre
Russells Hall Hospital
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Pensnett Road
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DY1 2HQ

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

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
The current data sharing plans for this study are unknown and will be 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?
Results article		28/11/2022	29/11/2023	Yes	No
Results article	embedded qualitative feasibility results	23/01/2023	29/11/2023	Yes	No
Results article		29/01/2024	09/04/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results			09/04/2024	No	No
Protocol file	version v1.0	01/12/2020	04/02/2021	No	No