Health Technology Assessment

Intravascular lithotripsy in peripheral arterial disease

This opportunity is now closed

Overview

Opportunity status:	Closed
Type:	Programme
Opening date:	5 August 2024
Closing date:	27 November 2024 at 1:00 pm
Reference ID:	2473

The Health Technology Assessment (HTA) Programme is accepting Stage 1 applications to their commissioned workstream for this primary research topic.

Timeline

27 November 2024

Stage 1 deadline

January 2025

Applications considered by the HTA Funding Committee. Shortlisted Stage 1 applicants will be given 8 weeks to submit a Stage 2 application.

May 2025

Stage 2 applications considered by the HTA Funding Committee

This opportunity is now closed

You can review information about this funding opportunity in our application system

View details yid%3D0%26opportunitytypeid%3D28701%26defaultstatusid%3D37504%26providertoken%3DWXhLGV

Commissioning brief

Introduction

The aim of the Health Technology Assessment (HTA) Programme is to ensure that high quality research information on the clinical effectiveness, cost-effectiveness and broader impact of healthcare treatments and tests are produced in the most efficient way for those who plan, provide or receive care from NHS and social care services. The commissioned workstream invites applications in response to calls for research on specific questions which have been identified and prioritised for their importance to the NHS, patients and social care.

Research question

What is the clinical and cost effectiveness of using intravascular lithotripsy when revascularising the limbs of people with peripheral arterial disease?

1. Patient group: People with steno-occlusive peripheral arterial disease affecting their lower limbs, judged to be optimally managed endovascularly by the multidisciplinary team.
   Applicants to consider stratification or pre-specified sub-group analysis by TASC score and/or severity of calcification. Applications are encouraged which include recruitment from geographic populations with high disease burden which have been historically underserved by research activity in this field.
2. Intervention: Intravascular lithotripsy (IVL) as part of endovascular revascularisation.
3. Control: Standard endovascular revascularisation without the use of intravascular lithotripsy (applicants to define and justify).
4. Important outcomes: Amputation free survival; major or minor amputation; quality of life; length of hospital stay; functional ability; pain; cost-effectiveness.
   Other outcomes: Survival; adverse events; reintervention rates; vessel patency; acceptability; painkiller use; ulceration.
   Existing Core Outcomes should be included amongst the list of outcomes unless a good rationale is provided to do otherwise. Applicants are encouraged to report recruitment and

findings disaggregated by sex (and other demographic factors where relevant).

5. Study design: A randomised controlled trial with an internal pilot phase to test key trial processes such as recruitment and adherence. Clear stop/go criteria should be provided to inform progression from pilot to full trial.
6. Setting: Secondary care.
7. Minimum duration of follow-up: Applicants to define and justify.

Rationale

Peripheral arterial disease (PAD) is most often caused by atherosclerosis, the build-up of hard calcium rich cholesterol plaques which cause narrowing (stenosis) or even blockage (occlusion) of the arteries, which severely limits blood flow to the lower limbs. It is associated with advanced age, smoking, diabetes and chronic renal dysfunction.

Given the ageing population and increase in diabetes in particular, the incidence and prevalence of PAD continues to rapidly grow. PAD can cause muscle pain on exercise (intermittent claudication), rest pain, ulceration and gangrene (chronic limb threatening ischaemia: CLTI), and is associated with significant morbidity, high risk of limb amputation and death. Below-knee (crural) arteries typically become increasingly involved as the overall severity of disease worsens, and are particularly challenging to treat.

In addition to management of pain and treatment of any concomitant infection in the affected limb(s), revascularisation (improving blood flow) is the cornerstone of treatment, with a variety of options available depending on the severity of disease and associated multiple long-term conditions. Bypass grafting (attaching a tube above and below the blocked artery) is more often considered for diffuse disease and/or in younger patients, while balloon angioplasty (stretching the narrowed/blocked artery with a small balloon on end of a small wire), with or without stenting, is used more commonly in those deemed not suitable for surgery.

Intravascular lithotripsy (IVL) is a relatively new procedure utilising an existing technology. Already used for the treatment of kidney, bladder, ureter and gallbladder stones, IVL uses very localised shockwaves, delivered via a catheter (like in balloon angioplasty) to break down the calcified plaques blocking the arteries and restricting blood flow, rather than just pushing the plaque into the vessel wall.

The limited evidence to date, synthesised in a recent NICE interventional procedure guideline, indicates that IVL for PAD is safe and effective, and it is starting to be used more widely. As yet this has not been tested in a large adequately powered randomised trial of patients (representative of those commonly seen and treated within the NHS) who are deemed optimally managed

endovascularly. Cost-effectiveness is also uncertain.

Additional background information

A background document is available that provides further information to support applicants for this call. It is intended to summarise what prompted the call and the existing evidence base, including relevant work from the HTA and wider NIHR research portfolio. It was researched and written on the basis of information from a search of relevant sources and databases, and in consultation with a number of experts in the field. If you would like a copy, please email htaresearchers@nihr.ac.uk (mailto:htaresearchers@nihr.ac.uk).

Making an application

Your application must be submitted online no later than 1pm on 27 November 2024. Applications will be considered by the HTA Funding Committee at its meeting in January 2025.

Shortlisted Stage 1 applicants will be given 8 weeks to submit a Stage 2 application. The Stage 2 application will be considered at the Funding Committee in May 2025.

For commissioned topics, the Programme strongly discourages the practice of the same co-applicant joining more than one competing team, other than in unusual circumstances (for example, a lead from a named charity or a unique national expert in a condition).

For such exceptions, each application needs to state the case as to why the same person is included. The shared co-applicant should not divulge application details between teams, and both teams should acknowledge in their application that they are aware of the situation, and that study details have not been shared.

Should you have any queries please contact htacommissioning@nihr.ac.uk (mailto:htacommissioning@nihr.ac.uk).

Application support

In order to apply you will need to carefully review the:

- Stage 1 application supporting information (/documents/hta-programme-supporting-information-realms/27265)
- Stage 1 guidance notes (/documents/hta-programme-stage-1-guidance-notes-realms/27147)
- HTA tips for applicants (https://www.nihr.ac.uk/hta-tips-applicants)

Applications received by the advertised closing date will be considered at a first-stage funding committee meeting, and successful applicants will then be invited to submit a Stage 2 application. Applicants will have 8 weeks to complete and submit their Stage 2 application form, which will then be considered at the following HTA funding committee meeting. For more information, please read the commissioning brief.

All primary research projects are expected to establish a programme appointed Study Steering Committee and it is important that you read the Research Governance Guidance (/documents/research-governance-guidelines/12154) before completing your application. Costs incurred by this committee should be included in the budget as appropriate.

Studies within a trial or review

This funding opportunity is eligible for a SWAT/SWAR (study within a trial or study within a review), which can help significantly improve methodology of future research as well as the host study. Find out about the benefits of SWATs/SWARs and how to include one in your application (https://www.nihr.ac.uk/methodological-sub-studies-studies-within-trial-or-project-swat-and-studies-within-review-swar).

Word version of the Stage 1 application form

Download a template of the application form below.

Please note that the Word version of the Stage 1 application form is to be used as a guide and to assist with completion of the online application form only, for example to see how many characters are accepted in each section and how the printed complete form is laid out. Please do not try to use this as an application form, you must apply using the online form available through the links available when calls are open. You should also refer to the application form guidance notes.

(/media/21716/download/)

Word-realms-version-stage-1-application-form.docx

DOCX

Last updated: 12 September 2024

Download document (124.92 KB)

Contact Details

- For help with your application contact htafunding@nihr.ac.uk (mailto:htafunding@nihr.ac.uk)
- For more information about the funding Programme, visit the HTA page (/node/62891)
- Got a research idea and not sure how to turn it into a funding application? The NIHR Research Support Service (RSS) supports researchers in England to apply for funding, and to develop and deliver clinical and applied health, social care and public health research post award. Find out how the RSS can help you (https://www.nihr.ac.uk/explore-nihr/support/research-support-service/) .