ISRCTN31383218 https://doi.org/10.1186/ISRCTN31383218

The Hull and East Yorkshire Angioplasty (HEYA): A study investigating the effects of balloon inflation time on patient quality of life outcomes and long term arterial patency in the superficial femoral and popliteal arteries

Submission date	**Recruitment status**	[X] Prospectively registered
02/02/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/03/2014	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/05/2015	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Peripheral Arterial Disease (PAD) is a disease that is caused by accumulation of fatty deposits in the blood vessels that supply the leg muscles. In the western world, it affects 20% of adults older than 55 years. This is about 27 million people in Europe and the United States. This disease can be silent in nature with patients presenting to their doctor with intermittent pain associated with exercise and relieved by rest. The treatment, called Peripheral Transluminal Angioplasty (PTA), involves puncturing an artery in the leg and inserting a balloon that will be inflated at the point of blockage to increase the blood supply to the leg. At present, there is very little evidence regarding the most effective length of time for balloon inflation, and the long- term effect depends on the operator and the centre. With this study we aim to find out if using a specific balloon inflation time can improve the treatment outcomes and the patient's quality of life.

Who can participate?

This study aims to recruit 50 patients suffering from symptomatic arteriosclerotic disease and who have been selected to undergo Peripheral Transluminal Angioplasty (PTA).

What does the study involve?

PTA will involve puncture of an artery in the leg and insertion of a balloon that will be inflated at the point of blockage to increase the blood supply to your leg. Patients will be allocated randomly into one of two groups: a 60 second group or a 180 second group. If you are in the 60 second group and the initial inflation fails, then a further 180 second inflation will be performed. If further treatment is required after the balloon inflation has occurred then this will be performed. This will lead to four groups of patients:

1. Successful angioplasty with 60 seconds
2. Successful angioplasty with 180 seconds
3. Successful angioplasty with 60 + 180 seconds

4. Unsuccessful angioplasty requiring further immediate treatment
Patients will then take part in a questionnaire that will ask about exercise tolerance and general well-being. Follow up will be at 8 weeks, where the patient will be checked after post procedure and their blood pressure readings are taken. The 1-year follow-up is an appointment specifically for those patients in the study and will involve repeat questionnaires to see the effect on quality of life and exercise capacity.

What are the possible benefits and risks of participating?
There is no clinical benefit to participating in the study. However, taking part in a clinical study is a rewarding process. There are no additional risks from undertaking this study. The general risks of the procedure are bleeding and infection

Where is the study run?
The study will be run at the Hull Royal Infirmary, UK.

When is the study starting and how long is it expected to run for?
The trial is expected to start recruitment from late March to early April 2014 and will aim to finish mid-2015, with full follow-up of patients performed by mid-2016.

Who is funding the study?
The British Society of Interventional Radiology (BSIR), UK.

Who is the main contact?
Dr Aubrey Smith
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
13/YH/0407

Study information

Scientific Title

Hull and East Yorkshire Angioplasty (HEYA) pilot study and randomised controlled trial

Acronym
HEYA

Study objectives
Null hypothesis: Balloon angioplasty inflation time does not affect quality of life outcomes and long-term arterial patency in the peripheral arterial tree.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Humber Bridge, 15/01/2014, ref.:13/YH/0407

Primary study design
Interventional

Study design
Three-year pilot study designed as an randomised controlled trial (RCT)

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Claudication

Interventions
Peripheral Transluminal Angioplasty of the superficial femoral and popliteal artery will involve puncture of an artery in the leg and insertion of a balloon that will be inflated at the point of blockage to increase the blood supply to your leg. Patients will be randomly allocated to one of two groups:
Group 1: a 60 second balloon angioplasty inflation time
Group 2: a 180 second balloon angioplasty inflation time

Intervention Type
Procedure/Surgery

Primary outcome(s)
Balloon angioplasty time effect on patient's quality of life
1. Subjective: Walking Impairment Questionnaire.
2. Objective: Short Form 36 (SF-36)
3. Cost-effectiveness analysis: SF-6D

Key secondary outcome(s)
Assessment of post angiographic outcome:
1. Pre-procedure assessment of vasculature
1.1. USS Duplex or
1.2. MRA
2. Immediate Post Procedure Angiographic assessment. Images scored by two independent observers using the Hull 'Pre and post angioplasty scoring' and peripheral run off weighting

score.
3. Post Angiographic outcome
3.1. ABPI post procedure (at 8 weeks and 1 year).
3.2. USS Duplex 1 year. Measurement of waveform and peak velocities to assess stenosis post angioplasty
4. Re-intervention rate
Re-intervention will be recorded at follow up and interpreted as 'immediate': If the initial angioplasty at time of procedure has failed to prevent the stenosis and further treatment is required then this would constitute 'Immediate re-intervention'. Post angioplasty intervention is any other intervention, radiological or surgical, that is required in the time period of the study after the procedure has been performed.

Completion date
31/08/2016

Eligibility

Key inclusion criteria
Any patient (Male and Female over age 18, no age limit) with symptomatic arteriosclerotic disease of the Superficial Femoral and Popliteal Artery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Pre-procedure
1. Patient presenting with critical limb ischaemia
2. If no peripheral run off present (TASC D lesions greater than 4 cm)
3. Patient lacks capacity i.e requires Consent Form 4
4. Patient identified as being on any other trial
5. Calcium channel blocker
6. Concurrent Iliac disease.
7. Total lesion size greater than 10 cm
8. <18 years of age
9. Pregnant

Procedure
1. Patient is deemed unfit for procedure

2. Patient unable to tolerate allotted balloon inflation time
3. Severe unforeseen complication e.g. anaphylaxis

Date of first enrolment
01/04/2014

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hull Royal Infirmary
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Charity

Funder Name
British Society of Interventional Radiology (BSIR) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No