

The effectiveness and cost-effectiveness of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for trauma

Submission date 14/08/2017	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 23/08/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/09/2024	Condition category Injury, Occupational Diseases, Poisoning	☐ Individual participant data

Plain English summary of protocol

Background and study aims

In the UK around 5800 people die annually after being severely injured. One reason these patients die is because they have suffered from massive internal bleeding. If a way was found to stop this bleeding, lives could be saved. A new treatment has been developed that could help – it is called REBOA (Resuscitative Endovascular Balloon Occlusion of the Aorta). REBOA involves doctors inserting a small balloon directly into the patient's main artery and inflating it. The balloon then blocks the artery, temporarily stopping the blood flow. Stopping the blood flow in this way gives doctors time to operate. It also helps to keep blood circulating to the brain and heart. However, the parts of the body below the balloon are cut off from the normal blood flow and this may result in short- or longer-term problems. REBOA has not been widely used because it is new, complicated to learn and it is not certain how safe and effective it is. Only three studies have compared patients who have received REBOA against those who did not, and the results are conflicting – two studies showed REBOA was better, the other that it was worse. In England, severely injured patients are treated in Major Trauma Centres. One Major Trauma Centre in London has now introduced REBOA and many other UK hospitals are also interested in using this technique. It is therefore important to test whether it is better or worse to use REBOA before it is used more widely in the NHS. The aim of this study is to assess the clinical and cost-effectiveness of standard major trauma centre treatment plus REBOA, compared with standard major trauma centre treatment alone, for the management of life-threatening torso haemorrhage (bleeding) in UK major trauma centres.

Who can participate?

Patients aged 16 or older with life-threatening torso haemorrhage

What does the study involve?

Participants are randomly allocated to receive either the standard major trauma centre treatment, or the standard major trauma centre treatment plus REBOA. All participants are followed up for 6 months.

What are the possible benefits and risks of participating?

Participating will help to collect more information about REBOA so that future patients with life-threatening bleeding caused by injury can be treated better. The risks of taking part are small. Most people with life-threatening haemorrhage remember very little about their initial treatment, but there is a possibility that receiving a questionnaire or a visit from a researcher could be upsetting later on.

Where is the study run from?

University of Aberdeen (UK)

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

April 2017 to March 2023

Who is funding the study?

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) (UK)

Who is the main contact?

Ms Gillian Ferry, gillian.ferry@abdn.ac.uk

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Central Portfolio Management System (CPMS)

35059

Study information

Scientific Title

A randomised controlled trial of the effectiveness, and cost-effectiveness, of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for trauma

Study objectives

The aim of this study is to establish, via a randomised controlled trial, the clinical and cost-effectiveness of standard major trauma centre treatment plus Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA), compared with standard major trauma centre treatment alone, for the management of life-threatening torso haemorrhage in UK major trauma centres.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West Greater Manchester South, 26/06/2017, ref: 17/NW/0352

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Treatment, Device

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Life-threatening torso haemorrhage

Interventions

Recruitment is by means of a dedicated and secure website accessible from any brand of handheld device, including smartphones (the preferred option) and tablets (one of which will be provided for each centre). The recruitment of a participant only requires the trauma team leader to enter the patient's hospital number. This information, together with the site's and TTL's details (as previously entered) then links directly to CHaRT's online randomisation system (which will adopt randomisation by blocks of randomly varying length), which returns the patient's allocation, to either:

1. Standard major trauma centre treatment
2. Standard major trauma centre treatment plus REBOA

For those randomised to receiving REBOA treatment, the treatment with the REBOA balloon is unlikely to exceed 1 hour. All patients will be followed up for a total of 6 months post randomisation.

Intervention Type

Other

Primary outcome(s)

Primary clinical outcome:

90-day mortality, defined as death within 90 days of injury, before or after discharge from hospital. This outcome is intended to capture any late harmful effects

Primary economic outcome:

Lifetime incremental cost per QALY gained, from a health and personal social services perspective

Key secondary outcome(s)

Secondary clinical outcomes are all gathered from patient notes/TARN notes and include:

1. In-hospital mortality
2. 6-month mortality
3. Length of stay (in hospital and intensive care unit)
4. 24h blood product use (from injury)
5. Need for haemorrhage control procedure (operation or angioembolisation), defined as whether such a procedure was required (from time of injury)
6. Time from admission to commencement of haemorrhage control procedure (REBOA, operation, or angioembolisation), defined as time to balloon inflation, incision, or first angiogram
7. Complications
8. Functional outcome, measured using the extended Glasgow Outcome Score) at 6 months

Secondary economic outcomes include:

1. 6-month costs from an NHS and from a patient and social services perspective
2. Quality of life, measured using EQ-5D-5L at 6-month follow up
3. Incremental cost per QALY gained at 6 months

Completion date

31/03/2023

Eligibility

Key inclusion criteria

1. Adult trauma patients (aged, or believed to be aged, 16 or older)
2. Confirmed or suspected life-threatening torso haemorrhage which is thought to be amenable to adjunctive treatment with REBOA (zone I or zone III)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

90

Key exclusion criteria

1. Women known or thought to be pregnant at presentation
2. Children (aged, or believed to be aged 15 or younger)
3. Patients with injuries which are deemed unsurvivable on clinical grounds

Date of first enrolment

01/10/2017

Date of final enrolment

30/03/2022

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Leeds Major Trauma Centre

Leeds General Infirmary

Great George Street

Leeds

United Kingdom

LS1 3EX

Study participating centre

St Marys Major Trauma Centre

Praed Street

London

United Kingdom

W2 1NY

Study participating centre

Nottingham Major Trauma Centre

Queens Medical Centre

Derby Road

Nottingham

United Kingdom

NG7 2UH

Study participating centre

Royal Hospital London Barts Health NHS Trust
The Royal London Hospital Emergency Department
Ground Floor Central Tower
London
United Kingdom
E1 1BB

Study participating centre
Queen Elizabeth Hospital Birmingham
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospitals Coventry and Warwickshire
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre

Royal Victoria Infirmary

Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre**John Radcliffe Hospital**

Oxford University Hospitals NHS Foundation Trust
Headley Way
Oxford
United Kingdom
OX3 9DU

Study participating centre**Royal Hallamshire Hospital**

Sheffield Teaching Hospitals NHS Foundation Trust
Glossop Road
Sheffield
United Kingdom
S10 2JF

Study participating centre**St George's University Hospitals NHS Foundation Trust**

Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre**Royal Stoke University Hospital**

University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Sponsor information

Organisation

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 14/199/09

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to patient confidentiality.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/10/2023	16/10/2023	Yes	No
Results article		01/09/2024	12/09/2024	Yes	No
Protocol article		12/05/2022	16/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Interim results article		12/05/2022	16/05/2022	Yes	No
Protocol file	version V2	20/07/2017	02/04/2019	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes