# 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	[X] Prospectively registered		
		[X] Protocol		
Registration date 23/08/2017	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 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 costeffectiveness 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

#### Study website

https://w3.abdn.ac.uk/hsru/REBOA/Public/Public/index.cshtml

# Contact information

#### Type(s)

Scientific

#### Contact name

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# Additional identifiers

EudraCT/CTIS number

**IRAS** number

#### ClinicalTrials.gov number

#### Secondary identifying numbers

**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 costeffectiveness 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

#### Study design

Randomised; Interventional; Design type: Treatment, Device

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

# 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 measure

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

#### Secondary outcome measures

Secondary clinical outcomes are all gathered form 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

#### Overall study start date

01/04/2017

#### 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

#### Age group

Adult

#### Sex

Both

# Target number of participants

Planned Sample Size: 120; UK Sample Size: 120

#### 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

England

United Kingdom

# 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

University of Aberdeen and NHS Grampian

#### Sponsor details

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#### Sponsor type

Hospital/treatment centre

#### Website

http://www.abdn.ac.uk/clinicalresearchgovernance/

# Funder(s)

#### Funder type

Government

#### **Funder Name**

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

# **Results and Publications**

# Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal in 2021.

#### Intention to publish date

31/08/2023

# 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	<b>Details</b> version V2	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		20/07/2017	02/04/2019	No	No
Interim results article		12/05/2022	16/05/2022	Yes	No
<u>Protocol article</u>		12/05/2022	16/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		12/10/2023	16/10/2023	Yes	No
Results article		01/09/2024	12/09/2024	Yes	No