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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

Registration date
23/08/2017

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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

Contact information

Type(s)
Scientific

Contact name
Ms Gillian Ferry

ORCID ID
http://orcid.org/0009-0006-9012-9271

Contact details
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
University of Aberdeen
Health Sciences Building
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD
+44 (0)1224 438124
gillian.ferry@abdn.ac.uk

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 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

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
c/o Ms Patricia Burns
Research Governance Manager
Foresterhill House Annexe
Foresterhill
Aberdeen
Scotland
United Kingdom
AB25 2ZB
+44 (0)1224 554362
researchgovernance@abdn.ac.uk

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V2	20/07/2017	02/04/2019	No	No
Interim results article		12/05/2022	16/05/2022	Yes	No
Protocol article		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