ISRCTN40090372 https://doi.org/10.1186/ISRCTN40090372

A trial comparing short course antibiotics and standard course antibiotics for the treatment of sepsis

Submission date
07/11/2023

Recruitment status
Recruiting

Registration date
12/12/2023

Overall study status
Ongoing

Last Edited
06/11/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Sepsis is a life-threating condition due to a severe infection. It is a common reason for patients to require “life-support”. Sepsis is a leading cause of death worldwide.

Antibiotics are a major part of the treatment of sepsis, but antibiotics also carry significant risks. The overuse of antibiotics promotes the emergence of “superbugs”, can also be toxic to organs such as the liver and can occasionally be responsible for life-threatening bowel infections.

Striking the right balance of using antibiotics appropriately, while avoiding their potential harm, is a challenge. Antibiotics are initiated rapidly for sepsis because of the severity of illness but once started, the exact duration needed to treat an infection adequately is unknown. Determining a duration of antibiotics that effectively treats sepsis, but is not unnecessarily prolonged, could have a big impact on antibiotic use overall.

We aim to determine whether short-duration antibiotic treatment is as good as routine practice, which is usually a longer duration of antibiotics, for critically ill patients with sepsis.

We will carry out a clinical trial including adult patients with sepsis who are admitted to a critical care unit. We will randomly allocate patients to receive a short fixed-course of antibiotics (5 days) or usual care (this is typically a 9-day course). This trial will only specify the duration of antibiotics, and the clinical team will know what duration the patient is getting. The choice or combination of antibiotics will be decided by the clinical team. All patients will have antibiotics managed according to standard antibiotic stewardship practice. The only difference between the two trial groups is that the short-duration group will have 5 days of antibiotics.

We will determine whether short-course antibiotic treatment is as effective as routine practice by assessing clinical outcomes for patients when they are in hospital and at 90-day follow-up.

Who can participate?
The SHORTER trial will recruit adults patients (aged 18 or over) who are being treated in a critical care setting for suspected or confirmed sepsis.

What does the study involve?
Antibiotics are essential in treating sepsis. But we also know that there are side effects of being treated with antibiotics, especially in people being treated in an intensive care setting. These include developing more infections, some of these might not respond to antibiotic treatment, and side effects in the body especially the kidneys. Commonly antibiotics are given for 7 or more days to treat sepsis. In the SHORTER trial we want to know whether we can safely and effectively treat sepsis with a shorter 5-day course of antibiotics and what effect this would have on patients.
Participants hospital stay will not change at all. Participants will be selected at random, by a computer, to take part in the intervention arm or control arm of the trial. If taking part in the intervention arm participants will have a short 5 day course of antibiotics to treat their sepsis, if taking part on the control arm participants will have the length of their antibiotics chosen by their hospital team, typically this will be 7 or more days of antibiotics.
Participants will take part in the trial for up to 90 days (approximately 3 months). Up to 90 days data will be collected from participants' medical records. At 90 days participants will be contacted and asked to complete some trial questionnaires.

What are the potential benefits and risks of participating?
Participants may experience some potential benefits but it is also possible that they do not have any direct benefit. Though, participation could influence the treatment patients with sepsis receive in the future.
The main risk is if antibiotics are stopped before the infection is treated fully. Hospital teams will monitor participants' health closely, as they would normally, to ensure that they are not put at risk. If participants need to continue receiving antibiotics for longer, then they will be given these without hesitation. Participant safety always comes first. If this does happen data will still be used for the trial.

Where is the study run from?
The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2023 to August 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
SHORTER.Trial@newcastle.ac.uk

Contact information

Type(s)
Scientific

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SHORTER.Trial@newcastle.ac.uk

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Scientific

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+44 191 208 2422
SHORTER.Trial@newcastle.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
317788

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 57052, NIHR134101, IRAS 317788

Study information

Scientific Title
A randomised controlled trial of SHORT duration antibiotic thERapy for critically ill patients with sepsis

Acronym
SHORTER

Study objectives

Current study objectives as of 06/11/2025:

1. To determine whether short duration antibiotic therapy is as good as standard care in treating sepsis in terms of mortality and whether it reduces overall antibiotic exposure.
2. To assess the effect of short duration antibiotic therapy on:
2.1. Suspected clinically relevant antibiotic-associated adverse events
2.2. Length of critical care unit stay
2.3. Length of hospital-stay
2.4. Rate of further/recurrence of infections
2.5. Readmission to critical care or hospital
3. Health Economic analysis:
3.1. Is short course antibiotic therapy cost effective compared to usual care at 90 days post intervention?
3.2. Is short course antibiotic therapy cost effective compared to usual care over the patient's lifetime?
4. Process Evaluation:
4.1. To understand the implementation of the trial protocol and willingness of clinicians to follow a fixed short-duration intervention.

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3. Health Economic analysis:
3.1. Is short course antibiotic therapy cost effective compared to usual care at 90 days post intervention
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4. Process Evaluation:
4.1. To understand the implementation of the trial protocol and willingness of clinicians to follow a fixed short-duration intervention

Ethics approval required

Ethics approval required

Ethics approval(s)

1. approved 12/09/2023, Wales REC 4 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922 940989; Wales.REC4@wales.nhs.uk), ref: 23/WA/0197

2. approved 01/05/2024, Scotland A Research Ethics Committee (2nd Floor, Waverley Gate 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 781 460 9032; sesres@nhslothian.scot.nhs.uk), ref: 24/SS/0013

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Current interventions as of 06/11/2025:

Patients will be randomised to one of two arms; the intervention arm and the comparator arm. Participants randomised to the intervention arm will have the duration of antibiotics adjusted to a 5-day course. This duration commences from the initiation of antibiotics. This short course of antibiotics relates only to the initial course of antibiotics and to its duration. The choice of antibiotics will be according to the clinical team.

Duration of antibiotics in the comparator arm will be according to best practice and guidelines as per standard care. All other aspects of care between the two trial groups will be according to best practice, including antibiotic adjustments according to test results and antibiotic stewardship multi-disciplinary team involvement.

Participant follow up will extend to 90-days. Outcome data will be collected from clinical records and routinely collected electronic data including Intensive Care audit bodies such as Intensive Care National Audit & Research Centre (ICNARC). The majority of outcome data will be collected before participants are discharged from hospital. Participants will be asked to complete questionnaires for health economic analysis (quality of life, time and travel) at 90 days. Participants will be contacted by telephone or post if discharged by this point.

In summary, patients will be screened for eligibility and have antibiotic duration for sepsis adjusted if randomised to the intervention arm. All other aspects of routine care will be unchanged. Participants will be followed up for 90 days following randomisation. The majority of outcome data will be collected from clinical records or routine electronic data sources. Participants will be asked to complete questionnaires at 90-day follow up for health economic analysis.

Process Evaluation:
We will utilise mixed methods, using purposive sampled qualitative data together with quantitative data from the trial. Data will be collected during the following stages of the trial:
1. Pre-trial: We will assess the current practice of antibiotic use with a baseline questionnaire sent to all sites.
2. During the internal pilot: In a purposive sample of 10 sites (max of 40 participants) we will

administer the Normalisation Measure Development survey instrument (NoMAD-23 item) and conduct interviews with clinical staff to determine the acceptability of the trial protocol.
3. During the main study: We will conduct semi-structured interviews (either face-to-face or remotely via tele/video conferencing) with clinical staff from approximately 10 sites (max of 40 participants) to assess the implementation and acceptability of the intervention and clinical decisions affecting fidelity to the trial protocol. We will also conduct non-participant observations to understand the decision-making process related to antibiotic use.
4. Final site visits: We will conduct semi-structured interviews (either face-to-face or via tele /video conferencing) with staff (max of 40 participants) in purposively selected 10 sites involved in the intervention delivery to reflect on the use of the trial protocol, including perceived barriers, enablers, and work processes affecting antibiotic prescribing practice.

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Previous interventions as of 22/04/2024:

Patients will be randomised to one of two arms; the intervention arm and the comparator arm. Participants randomised to the intervention arm, will have the duration of antibiotics adjusted to a 5-day course. This duration commences from the initiation of antibiotics. This short course of antibiotics relates only to the initial course of antibiotics and to its duration. The choice of antibiotics will be according to the clinical team.

Duration of antibiotics in the comparator arm will be according to best practice and guidelines as per standard care. All other aspects of care between the two trial groups will be according to best practice, including antibiotic adjustments according to test results and antibiotic stewardship multi-disciplinary team involvement.

Participant follow up will extend to 90-days. Outcome data will be collected from clinical records and routinely collected electronic data including Intensive Care audit bodies such as Intensive Care National Audit & Research Centre (ICNARC). The majority of outcome data will be collected before participants are discharged from hospital. Participants will be asked to complete questionnaires for health economic analysis (quality of life, time and travel) at 90 days. Participants will be contacted by telephone if discharged by this point.

In summary, patients will be screened for eligibility and have antibiotic duration for sepsis adjusted if randomised to the intervention arm. All other aspects of routine care will be unchanged. Participants will be followed up for 90 days following randomisation. The majority of outcome data will be collected from clinical records or routine electronic data sources. Participants will be asked to complete questionnaires at 90-day follow up for health economic analysis.

Process Evaluation:
We will utilise mixed methods, using purposive sampled qualitative data together with quantitative data from the trial. Data will be collected during the following stages of the trial:
1. Pre-trial: We will assess the current practice of antibiotic use with a baseline questionnaire sent to all 50 sites.
2. During the internal pilot: In a purposive sample of 10 sites (max of 40 participants) we will administer the Normalisation Measure Development survey instrument (NoMAD-23 item) and conduct interviews with clinical staff to determine the acceptability of the trial protocol.
3. During the main study: We will conduct semi-structured interviews (either face-to-face or remotely via tele/video conferencing) with clinical staff from approximately 10 sites (max of 40 participants) to assess the implementation and acceptability of the intervention and clinical

decisions affecting fidelity to the trial protocol. We will also conduct non-participant observations to understand the decision-making process related to antibiotic use.
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Duration of antibiotics in the comparator arm will be according to best practice and guidelines as per standard care. All other aspects of care between the two trial groups will be according to best practice, including antibiotic adjustments according to test results and antibiotic stewardship multi-disciplinary team involvement.

Participant follow up will extend to 90-days. Outcome data will be collected from clinical records and routinely collected electronic data including the Hospital Episode Statistics (HES), Office for National Statistics (ONS) and Intensive Care audit bodies such as Intensive Care National Audit & Research Centre (ICNARC). The majority of outcome data will be collected before participants are discharged from hospital. Participants will be asked to complete questionnaires for health economic analysis (quality of life, time and travel) at 90 days. Participants will be contacted by telephone if discharged by this point.

In summary, patients will be screened for eligibility and have antibiotic duration for sepsis adjusted if randomised to the intervention arm. All other aspects of routine care will be unchanged. Participants will be followed up for 90 days following randomisation. The majority of outcome data will be collected from clinical records or routine electronic data sources. Participants will be asked to complete questionnaires at 90-day follow up for health economic analysis.

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2. During the internal pilot: In a purposive sample of 10 sites (max of 40 participants) we will administer the Normalisation Measure Development survey instrument (NoMAD-23 item) and conduct interviews with clinical staff to determine the acceptability of the trial protocol.
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Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Antibiotics

Primary outcome(s)
Measured using patient records:
1. 28-day all-cause mortality (non-inferiority safety outcome)
2. Total antibiotic treatment days measured at 28 days (superiority clinical effectiveness outcome)

Key secondary outcome(s))
Current secondary outcome measures as of 06/11/2025:

1. All-cause mortality measured at 90 days
2. Suspected clinically relevant antibiotic-associated adverse events during index hospital admission occurring from randomisation up to hospital discharge
3. Length (number of days) of critical care unit stay for the initial index episode of sepsis measured up to 90 days
4. Length (number of days) of hospital stay measured up to 90 days
5. Number of further/recurrence of infections requiring additional antibiotic courses following the index sepsis episode, measured up to 28 days
6. Occurrence of readmission to critical care or hospital during the 90 day follow up period
7. Incremental cost per death avoided at 90 days measured using mortality data and the Health Resource Usage & Time and Travel Questionnaire
8. Incremental cost per Quality Adjusted Life Year (QALY) gained at 90 days measured using the EQ-5D-5L questionnaire
9. Cost-effectiveness acceptability curves (CEACs) to assess the probability of the intervention being considered cost-effective at different willingness-to-pay (WTP) thresholds for a gained QALY at 90 days measured using the EQ-5D-5L and Health Resource Usage & Time and Travel Questionnaires
10. Average healthcare costs per participant over 90 days for each area of resource use measured using the Health Resource Usage & Time and Travel Questionnaire
11. Utility scores derived from responses to the EQ-5D-5L questionnaire at 90 days
12. Average QALYs per participant at 90 days measured using the EQ-5D-5L questionnaire
13. Incremental cost per QALY gained over the patient's lifetime measured using the EQ-5D-5L questionnaire
14. Cost-effectiveness acceptability curves (CEACs) to assess the probability of the intervention being considered cost-effective at different willingness-to-pay (WTP) thresholds for a gained QALY over the participants lifetime measured using the EQ-5D-5L and Health Resource Usage & Time and Travel Questionnaires

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Completion date
31/08/2026

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 06/11/2025:

1. Adult patients, aged >=18 years, treated within a critical care setting (ICU or HDU) for suspected or confirmed sepsis due to either community- or hospital-acquired infections.
2. Evidence of new or worsening acute organ dysfunction resulting from suspected or confirmed infection (e.g. the treatment or monitoring of an organ dysfunction).
3. Antibiotics initiated for suspected or confirmed sepsis, patient is still receiving antibiotics at randomisation, and is able to be randomised within 4 days of the initiation of this course of antibiotics.

Process evaluation:
Clinical staff involved in everyday prescribing and/or managing of antibiotics within critical care.

Previous key inclusion criteria:

1. Adult patients, age >=18 years, treated within a critical care setting (ICU or HDU) for suspected or confirmed sepsis due to either community- or hospital-acquired infections.
2. Evidence of new or worsening acute organ dysfunction resulting from suspected or confirmed infection (e.g. the treatment or monitoring of an organ dysfunction).
3. Antibiotics initiated for suspected or confirmed sepsis and able to be randomised within 4 days of the initiation of this course of antibiotics

Process evaluation:
Clinical staff involved in everyday prescribing and/or managing of antibiotics within critical care.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current key exclusion criteria as of 06/11/2025:

1. Comorbidity with immunosuppression (e.g. Chemotherapy, maintenance steroids equivalent to > 10mg/day of prednisolone, post-transplantation).
2. Blood neutrophil count less than 0.5 x 10^9/L secondary to a pre-existing comorbidity.
3. Infection source where usual practice involves more than 14 days of antibiotics (e.g. undrainable abscess, endocarditis, Staphylococcus aureus bacteraemia, osteomyelitis).
4. Receiving end-of-life care.
5. Life-sustaining treatment expected to be withdrawn within the next 24 hours.
6. The clinician responsible for the patient's care is unable to adhere to the intervention.
7. Concomitant enrolment in another interventional trial, except where a co-enrolment agreement with SHORTER exists.

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Previous key exclusion criteria:

1. Comorbidity with immunosuppression (e.g. Chemotherapy, maintenance steroids equivalent to > 10mg/day of prednisolone, post-transplantation)
2. Blood neutrophil count less than 0.5 x 10^9/L secondary to a pre-existing comorbidity
3. Infection source where usual practice involves more than 14 days of antibiotics (e.g. undrainable abscess, endocarditis, Staphylococcus aureus bacteraemia, osteomyelitis)
4. Receiving end-of-life care

5. Life-sustaining treatment expected to be withdrawn within the next 24 hours.
6. The clinician responsible for the patient's care is unable to adhere to the intervention.

The following participant exclusion criteria was added on 03/03/2025:
7. Concomitant enrolment in another interventional trial, except where a co-enrolment agreement with SHORTER exists (a list of interventional trials approved for co-enrolment can be found on the trial website: https://www.shortertrial.com/).

Date of first enrolment
30/11/2023

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
The Whittington Hospital
Highgate Hill
London
United Kingdom
N19 5NF

Study participating centre
Kings College Hospital
Mapother House
De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AB

Study participating centre

Princess Royal University Hospital
Farnborough Common
Orpington
United Kingdom
BR6 8ND

Study participating centre
Ipswich Hospital
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Royal Papworth Hospital
Papworth Road
Cambridge Biomedical Campus
Cambridge
United Kingdom
CB2 0AY

Study participating centre
Sunderland Royal Hospital
Kayll Road

Sunderland
United Kingdom
SR4 7TP

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

Study participating centre
Milton Keynes General Hospital
Milton Keynes Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Queens Hospital
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
Northampton General Hospital
Cliftonville
Northampton
United Kingdom
NN1 5BD

Study participating centre
Rotherham General Hospital
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Study participating centre
William Harvey Hospital (ashford)
Kennington Road
Willesborough
Ashford
United Kingdom
TN24 0LZ

Study participating centre
Salisbury District Hospital
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Royal Cornwall Hospital (treliske)
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
SMCS at St Georges Hospital
St Georges Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre

Musgrove Park Hospital
Musgrove Park
Taunton
United Kingdom
TA1 5DA

Study participating centre
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Yeovil District Hospital
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Royal United Hospital
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Glan Clwd Hospital
Ysbyty Glan Clwydd
Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Study participating centre
University Hospital of North Durham
North Road
Durham
United Kingdom
DH1 5TW

Study participating centre
Queen Elizabeth Hospital
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
The Royal Oldham Hospital
Rochdale Road
Oldham
United Kingdom
OL1 2JH

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Study participating centre
St John's Hospital
Howden Road West
Howden
Livingston
West Lothian
Edinburgh
United Kingdom
EH54 6PP

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
United Kingdom
EH4 2XU

Study participating centre
Ulster Hospital
Upper Newtownards Rd
Dundonald
Belfast
United Kingdom
BT16 1RH

Study participating centre
Royal Shrewsbury Hospital
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre
Princess Royal Hospital
Sussex Mri Centre
Lewes Road
Haywards Heath
United Kingdom
RH16 4EX

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Study participating centre

Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
North Manchester General Hospital
Delaunays Road
Crumpsall
Manchester
United Kingdom
M8 5RB

Study participating centre
The Princess Alexandra Hospital
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
Antrim Area Hospital
45 Bush Rd
Antrim

United Kingdom
BT41 2RL

Study participating centre
City and Sandwell Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Aintree University Hospital
Lower Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
Good Hope Hospital
Rectory Road
Sutton Coldfield
United Kingdom
B75 7RR

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5SS

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Wexham Park Hospital
Wexham Street
Wexham
Slough
United Kingdom
SL2 4HL

Study participating centre
Bradford Royal Infirmary
Chesnut House
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Queens Hospital
Belvedere Road
Burton-on-trent
United Kingdom
DE13 0RB

Study participating centre
Altnagelvin Area Hospital
Glenshane Road
Londonderry

United Kingdom
BT47 6SB

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan
Data from this trial will be available to the scientific community subject to request and appropriate ethical approval. Requests for data should be directed to the Chief Investigator and Newcastle Clinical Trials Unit.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes