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

Submission date	Recruitment status Recruiting	<ul><li>Prospectively registered</li></ul>		
07/11/2023		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/12/2023	Ongoing	Results		
Last Edited	Condition category Infections and Infestations	Individual participant data		
06/11/2025		[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

Contact name
Ms Zoe Walmsley

#### **ORCID ID**

https://orcid.org/0000-0002-1253-6668

#### Contact details

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#### Type(s)

Scientific

#### Contact name

Mr Phil Mawson

#### **ORCID ID**

https://orcid.org/0000-0002-2056-5047

#### Contact details

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# 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.

#### Previous study objectives:

- 1. To determine whether short duration antibiotic therapy is as good asd standard care in treating sepsis in terms of mortality and whether it reduces overall antibiotic exposure
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- 2.2. Length of critical care unit stay
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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.

#### 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.

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#### **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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#### 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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- 1. All-cause mortality measured at 90 days
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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.
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- 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

Αll

#### 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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- 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 OSF

## 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

# 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes