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Does the use of fixed-extended-duration antibiotics improve patient outcomes compared to standard antibiotic durations in patients with complicated intra-abdominal infection?

Submission date
22/11/2021

Registration date
23/11/2021

Last Edited
12/11/2026

Recruitment status
No longer recruiting

Overall study status
Ongoing

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Bacteria live in the intestine to help digest food. If the intestine is damaged by an operation, injury or a disease such as cancer, bacteria can leak into the space surrounding the intestine. This is called the abdominal cavity. These bacteria cause serious infections known as complicated intra-abdominal infections. Over 30,000 patients per year suffer from this type of infection.
The care of patients with complicated intra-abdominal infections is a big concern for doctors. The damaged area of the intestine may need to be removed by surgery. Antibiotics are used to kill any bacteria left in the abdominal cavity. Sometimes this treatment does not work very well. In up to half of patients, the original infection recurs or they develop another infection. This means that these patients may need a second round of treatment. This might include antibiotics or an operation. Research from other trials has suggested that longer courses of antibiotics may offer benefits for patients with serious abdominal infections. If longer courses of antibiotics are better at curing and preventing infections, they may also be better at keeping patients out of hospital. This may reduce the chance that patients will catch antibiotic-resistant infections.
The aim of this study is to find out if longer antibiotic courses are better for patients with complicated intra-abdominal infections.

Who can participate?
Adults aged 16 years and over with complicated intra-abdominal infection.

What does the study involve?
The researchers will randomly allocate participants by chance into one of two treatment groups. One group will take antibiotics in accordance with the standard care duration at the recruiting site (typically 7 to 18 days), based on clinician judgment. Clinicians will use the clinical progress of the participant in combination with inflammatory blood markers, surgical and radiological findings, to guide antibiotic duration. The other group will take antibiotics for 4 weeks. In both arms, the choice and route of antibiotics will be based on the clinician's judgement. We will monitor patients in both groups over 6 months to see whether the treatments prevent the

return of the original infection and stop the development of new infections. The researchers will also ask patients to fill in a quality of life questionnaire which asks whether patients have any problems with mobility, self-care, their usual activities, pain/discomfort and anxiety/depression. This will be at 1, 3 and 6 months after they enrol in the trial. The researchers will also ask participants whether they have taken antibiotics or used any health care services as a result of their illness.

What are the possible benefits and risks of participating?
The potential benefits and disadvantages relate to the benefits and side effects of antibiotics. Shorter courses of antibiotics may be associated with an increased risk that the infection returns after stopping antibiotics. However, a longer course of antibiotics may result in more side effects from the antibiotics.
As a thank you for taking part, patients will be offered a £20 voucher at each follow-up timepoint.

Where is the study run from?
York Trials Unit (University of York) (UK)

When is the study starting and how long is it expected to run for?
January 2022 to January 2027

Who is funding the study?
The National Institute for Health and Care Research - Health Technology Assessment Programme (Project Number: NIHR131784) (UK)

Who is the main contact?
ytu-extend-trial@york.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

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Public

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT05148702

Integrated Research Application System (IRAS)
302989

National Institute for Health and Care Research (NIHR)
131784

Protocol serial number
HTA - , , IRAS Scotland 314513

Study information

Scientific Title
The EXTEND trial: EXTENDed antibiotic durations compared to standard antibiotic durations for patients with complicated intra-abdominal infection

Acronym
EXTEND

Study objectives
To determine if a fixed-extended-duration of 28-days antibiotic treatment is superior to standard care (typically 7-18 days of antibiotic treatment) based on clinical outcomes and quality of life assessed over six months of follow up.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/03/2022, Leeds West REC (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle Upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 972 2504; leedswest.rec@hra.nhs.uk), ref: 22/YH/0023

Primary study design
Interventional

Study design
Phase III multicentre open-label randomized controlled trial with internal pilot

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Complicated Intra-Abdominal Infection (cIAI)

Interventions
Current interventions as of 26/03/2024:

Randomisation process: Participants will be individually randomised 1:1 between 28-days antibiotics and standard care antibiotic duration using stratified block randomisation with randomly varying block sizes. Stratification will be by: postoperative cIAI vs non-postoperative cIAI, surgical source control procedure vs no surgical source control procedure and ICU stay vs no ICU stay within 10 days of randomisation.

Standard care antibiotic duration: clinicians use the clinical progress of the patient in combination with inflammatory blood markers, surgical and radiological findings to guide standard treatment antibiotic durations. The duration of treatment is not fixed.

Intervention arm treatment: the intervention is a strategy of a fixed-extended-duration antibiotic treatment. The treatment duration is fixed at 28-days duration, which is a longer (extended) treatment course than the duration of most antibiotic treatments for this condition.

In both trial arms the strategy relates to the duration of treatment only. The choice of antibiotic and route of administration are therefore selected by the treating clinician. Patients will be followed up for 180 days from the point of randomisation.

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Previous interventions:

Randomisation process: Participants will be individually randomised 1:1 between 28-days antibiotics and standard care antibiotic duration using stratified block randomisation with randomly varying block sizes. Stratification will be by: postoperative cIAI vs non-postoperative cIAI, surgical source control procedure vs no surgical source control procedure and ICU stay vs no ICU stay within 1 week of cIAI diagnosis.

Standard care antibiotic duration: clinicians use the clinical progress of the patient in combination with inflammatory blood markers, surgical and radiological findings to guide standard treatment antibiotic durations. The duration of treatment is not fixed.

Intervention arm treatment: the intervention is a strategy of a fixed-extended-duration antibiotic treatment. The treatment duration is fixed at 28-days duration, which is a longer (extended) treatment course than the duration of most antibiotic treatments for this condition.

In both trial arms the strategy relates to the duration of treatment only. The choice of antibiotic and route of administration are therefore selected by the treating clinician. Patients will be followed up for 180 days from the point of randomisation.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 26/03/2024:

Treatment failure within 180 days of randomisation. For in-patients, treatment failure is defined when a patient meets objective criteria for both inflammation and infection within a 5-day period. Meeting of the criteria for inflammation may precede or follow the date that criteria for infection were met (the first day of an eligible antibiotic treatment course). These criteria are:
Criteria for inflammation:
1.1 A fever (≥ 37.8 degrees Celsius) or hypothermia (≤36 degrees Celsius), plus
1.2 A neutrophilia (>7.5 x10^9/l) or neutropaenia (<1.8 x 109/L), plus
1.3 A CRP over 100 mg/l

PLUS, criteria for infection
2.1 Initiation of a new antibiotic treatment course of ≥ 5 days, or
2.2 A change in antibiotic treatment continued for ≥ 5 days, or
2.3 Initiation of a new antibiotic treatment, or a change in antibiotic treatment, and death within 5 days.

2.4 Bacteraemia with a recognised intestinal pathogen

New or changed antibiotic treatments must not be antibiotic prophylaxis, a change to achieve oral administration from intravenous antibiotics only, a change to reduce the spectrum of activity (targeted antibiotic treatment) or made due to antibiotic allergy only. New/changed antibiotics can include additional antibiotics, added to an ongoing treatment regimen. The first day of an eligible new/changed antibiotic treatment is called the antibiotic reference date. Inflammation 5 days either side of this antibiotic reference date can be assessed against the criteria for inflammation. A blinded endpoint committee will assess and classify data including but not limited to inflammation and antibiotic treatments to assign participants with treatment failure.

Once discharged, treatment failure requires re-admission to hospital and the in-patient criteria above to be met. Alternatively, they must have been admitted to hospital and have consumed antibiotics for > 48 hours prior to admission. Treatment failure cannot be assigned based on inflammation (fever, neutrophilia and CRP>100mg/L) detected within the 5 days after an operative procedure (surgical or radiological). Treatment failure can be assigned based on pre-operative inflammation and postoperative antibiotic changes. Treatment failure cannot be assigned due to evidence of inflammation or infection, as defined above, within the first 5 days of antibiotic treatment for the initial cIAI. If treatment is extended beyond the intervention duration this should be considered a new antibiotic treatment course.

Treatment failure measurement: A patient's temperature is measured as part of routine clinical care
two to four times daily and recorded in their medical records when in hospital. Patients have the neutrophil count and CRP measured, by means of a blood test, when admitted to hospital, or when an infection is suspected. It will be required that these blood tests are completed within 3 days of an
antibiotic prescription and monitored every 72 hours while receiving antibiotic therapy until there has been a reduction in CRP concentration of ≥25%, as per standard clinical practice. Patients' medication charts will be assessed to identify new or changed antibiotic consumption. A blinded endpoint committee will review evidence of inflammation plus antibiotic consumption, in combination with documented antibiotic allergies and microbiology reports, from the preceding two weeks. This review will determine if antibiotic consumption is a new or change in antibiotic treatment, and not prophylaxis, a change made to achieve a narrowing of spectrum, an oral switch only or made due to allergy only. The Data Monitoring and Ethics Committee will audit the blinded endpoint committee and the audit will be reviewed within the internal pilot.

Intestinal pathogens include: Anaerobes (e.g., Bacteroides), Enterobacterales (e.g., Citrobacter,E. coli, Enterobacter, Klebsiella, Serratia), Enterococcus spp., Pseudomonas spp. and Streptococcus species.

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Previous primary outcome measure:

Treatment failure within 180 days of randomisation. For in-patients, treatment failure is defined when a patient meets objective criteria for both inflammation and infection within a 5-day period. Meeting of the criteria for inflammation may precede or follow the date that criteria for infection were met (the first day of an eligible antibiotic treatment course). These criteria are:
Criteria for inflammation:
1.1 A fever (≥ 37.8 degrees Celsius), plus
1.2 A neutrophilia (>7.5 x10^9/l), plus
1.3 A CRP over 100 mg/l
Criteria for infection (measured using patient records)
2.1 Initiation of a new antibiotic treatment course of ≥ 5 days, or
2.2 A change in antibiotic treatment continued for ≥ 5 days, or
2.3 Initiation of a new antibiotic treatment, or a change in antibiotic treatment, and death within 5 days

Key secondary outcome(s)

Current secondary outcome measures as of 26/03/2024:

1. Quality of life measured using the EQ-5D-5L questionnaire completed by patients at baseline, 30, 90 and 180 days after randomisation.
2. Patients will be categorised according to the worst outcome they experience over the 6-month follow-up period using a four-level ordinal classification, the Desirability Of Outcome Ranking (DOOR). The four levels will be: 1. no treatment failure, 2. treatment failure (as for the primary outcome), 3. treatment failure associated with sepsis (NEWS 6 in ward-based patients and SOFA 2 in ICU based patients), 4. treatment failure associated with death. Measured over the 180 days after randomisation.
3. Number and type of source control procedures measured by reviewing patient notes at 180 days after randomisation. The definition of source control used for this study is any procedure

that stops the ongoing contamination of the peritoneal cavity and removes the majority of the contaminated intraperitoneal contents to the extent that no further acute interventions are felt to be necessary.
4. Relapse of cIAI measured by reviewing patient notes at 180 days after randomisation
5. All-cause mortality (time to event) measured by reviewing patient notes at 180 days after randomisation
6. Length of hospital stay measured by reviewing patient notes at 180 days after randomisation
7. Re-admission measured by reviewing patient notes at 180 days after randomisation
8. C. difficile infection measured by reviewing patient notes at 180 days after randomisation
9. Anti-microbial resistant (AMR) infections measured by reviewing patient notes at 180 days after randomisation. When standard treatment fails in patients with cIAI, antibiotics are often escalated to one of the carbapenem class of antibiotics. We will therefore use rates of carbapenem prescribing as a surrogate for AMR infections.
10. Days of antibiotic therapy (in-patient and outpatient) including anti-fungal therapy measured by reviewing patient notes and from a questionnaire completed by patients at 180 days after randomisation.
11. Acute kidney injury measured by reviewing patient notes at 180 days after randomisation and defined as: an increase in serum creatinine by ≥ 0.3 mg/dl (≥ 26.5 μmol/l) within 48 hours; or increase in serum creatinine to ≥ 1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; or urine volume < 0.5 ml/kg/h for 6 hours (KDIGO Clinical Practice Guideline for Acute Kidney Injury).

12. Complications
13. Number of days on ventilation and days of renal replacement therapy.
14.Time to treatment failure and number of episodes of treatment failure.
15. Resource use completed by participant questionnaires at 30, 90 and 180 days.

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Previous secondary outcome measures:

1. Quality of life measured using EQ-5D-5L questionnaire completed by patients at baseline, 30, 90 and 180 days after randomisation
2. Patients will be categorised according to the worst outcome they experience over the 6-month follow-up period using a four-level ordinal classification, the Desirability Of Outcome Ranking (DOOR). The four levels will be: 1. no treatment failure, 2. treatment failure (as for the primary outcome), 3. treatment failure associated with sepsis (NEWS 6 in ward-based patients and SOFA 2 in ICU based patients), 4. treatment failure associated with death. Measured at 180 days after randomisation.
3. Number and type of source control procedures measured by reviewing patient notes at 180 days after randomisation
4. Relapse of cIAI measured by reviewing patient notes at 180 days after randomisation
5. All-cause mortality measured by reviewing patient notes at 180 days after randomisation
6. Length of hospital stay measured by reviewing patient notes at 180 days after randomisation
7. Re-admission measured by reviewing patient notes at 180 days after randomisation
8. C. difficile infection measured by reviewing patient notes at 180 days after randomisation
9. Anti-microbial resistant (AMR) infections measured by reviewing patient notes at 180 days after randomisation
10. Days of antibiotic therapy (in-patient and outpatient) measured by reviewing patient notes and from a questionnaire completed by patients at 180 days after randomisation
11. Acute kidney injury measured by reviewing patient notes at 180 days after randomisation

Completion date
31/01/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/03/2024:

1. Adults (≥16 years) with complicated Intra-Abdominal Infection[1] (cIAI; see definition below)
2. Being treated with antibiotics until the point of randomisation, but within 10 days of initiation of effective antibiotic treatment for cIAI
3. Ability to provide informed consent by the patient or their consultee
4. More than 72 hours of further active in-patient management for the patient's cIAI is required (see below)
5. In the event that the patient is readmitted to hospital during the trial period, they are likely to be admitted to a hospital participating in the EXTEND trial

Patients will be included in the trial whether or not they undergo surgical or radiological source control procedures.

cIAI is defined by the following case definition:
1. A clinical presentation consistent with cIAI, plus
1.1. Fever (temperature of ≥37.8°C) and/or a neutrophilia (>7.5×10e9/L) and/or neutropaenia (<1.8 x 109/L) and/or intestinal pathogens cultured from sterile sites (closed peritoneum or blood) around the time of cIAI diagnosis, plus
1.2. Evidence of pathologic findings on radiologic examination, or
1.3. Evidence of pathologic findings at operation
2. The first day of effective antibiotic treatment will be determined by the patient's clinical team or clinical research team. Antibiotics that do not count towards these 10 days of effective treatment are:
2.1. Antibiotic prophylaxis e.g., penicillin for splenectomy, elective surgery antibiotic prophylaxis, UTI prophylaxis
2.2. Treatment for other infections that is not effective for cIAI e.g., cystitis. Antibiotics that are often used for cystitis and aren't effective for cIAI include Cephalexin, Fosfomycin Trimethoprim, Nitrofurantoin, and Pivmecillinam.
2.3. Oral antibiotics prescribed to treat infection prior to hospitalisation
2.4. Previous courses of treatment antibiotics: A previous course is one stopped for 48 hours or more
3. The further 72 hours starts from the first day of effective antibiotic treatment i.e., for a patient admitted to hospital with a cIAI, 3 days of admission are needed. Where a patient is already in hospital e.g., a postoperative patient, a further 3 days of admission are required starting from the point of the first day of effective antibiotic treatment.

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Previous inclusion criteria:

1. Adults (≥18 years) with complicated Intra-Abdominal Infection (cIAI; see definition below)
2. Being treated with antibiotics until the point of randomisation, but within 10 days of initiation of antibiotic treatment for cIAI
3. Ability to provide informed consent by the patient or their consultee.
4. More than 72 hours of active in-patient management for the patients cIAI is required

Specific inclusions where patients require more than 72 hours of in-patient management, are:
1. Patients with diverticulitis abscess
2. Perforated appendix with peri-appendiceal phlegmon, abscess or diffuse peritonitis (Grade 5 and 6 of the 2017 American Association for the Surgery on Trauma Grading System)
3. Discrete pancreatic infections (abscess, infected pseudocyst)
4. Patients will be included in the trial whether or not they undergo surgical or radiological source control procedures.

cIAI is defined by the following case definition:
1. A clinical presentation consistent with cIAI, plus
2. Fever (temperature of ≥37.8°C) and/or a neutrophilia (>7.5×10e9/L) and/or pathogens cultured from sterile sites (closed peritoneum or blood) with an intestinal pathogen, plus
3. Evidence of pathologic findings on radiologic examination, or
4. Evidence of pathologic findings at operation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 26/03/2024:

1. Perforated gastric ulcer or duodenal ulcer treated within 24 hours of the onset of symptoms.
2. Traumatic injury to the bowel (including iatrogenic or intraoperative) treated within 12 hours of injury.
3. Uncomplicated diverticulitis defined as an episode with a short history and with clinical signs of diverticulitis, with an increased body temperature and inflammatory parameters, verified by computed tomography (CT), and without any sign of complications such as abscess, free air or fistula.
4. Grade 1 to 3 appendicitis. To be eligible patient must have Grade 4 or 5 appendicitis defined by the 2017 American Association for the Surgery Trauma Grading System with either generalised peritonitis at surgery, or no or partial source control e.g. radiological drainage Non-perforated cholecystitis.
5. Ischemic or necrotic intestine without perforation.

6. Uterine perforation following uterine surgery treated within six hours of injury.
7. cIAIs with a low risk of complications who may receive more than 72 hours antibiotics are not intended to be included (such as those listed above : Traumatic injury to the bowel (including iatrogenic or intra-operative) treated within 12 hours of injury, Uterine perforation following uterine surgery treated within six hours of injury, Perforated gastric ulcer or duodenal ulcer treated within 24 hours of the onset of symptoms). Clinician assessment on the eligibility of patients receiving more than 72 hours of in-patient surgical care and antibiotics for their cIAI may be required in patients who have clinically improved at this point and do not require active surgical care but remain in hospital and on antibiotics.
8. Current enrolment in another trial dictating antibiotic treatment duration.
9. Previous Clostridium difficile infection.
10. Infected necrotic pancreatitis.
11. Concomitant infection requiring ≥4 weeks antibiotic therapy including intra-hepatic abscess /es planned to be treated with fixed-extended-duration antibiotics of 4 to 6 weeks antibiotics, osteomyelitis, and endocarditis.
12. Peritoneal dialysis.
13. Previously recruited for the EXTEND trial.
14. Treatment with Interleukin-6 Inhibitors.
15. High likelihood of death within 72 hours of cIAI randomisation in the opinion of the local Investigator.
16. Limitations in treatment decided before inclusion. Limitations in treatment that exclude patients from the EXTEND trial are those clinical decisions linked to an expectation the patient will die during this episode of infection.
17. Patient with persistent cIAI of more than 6 months duration.
18. A maximum of 20% of participants entering the trial can have a source of cIAI as the appendix. If 230 patients with appendix as the source are recruited, this will become an exclusion criteria for subsequent patients.

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Previous exclusion criteria:

1. Perforated gastric ulcer or duodenal ulcer treated within 24 hours of the onset of symptoms.
2. Traumatic injury to the bowel (including iatrogenic or intraoperative) treated within 12 hours of injury.
3. Uncomplicated diverticulitis defined as an episode with a short history and with clinical signs of diverticulitis, with an increased body temperature and inflammatory parameters, verified by computed tomography (CT), and without any sign of complications such as abscess, free air or fistula.
4. Non-perforated, nongangrenous appendicitis (Grade 4 and below of the 2017 American Association for the Surgery on Trauma Grading System) or cholecystitis.
5. Ischemic or necrotic intestine without perforation
6. Uterine perforation following uterine surgery treated <six hours following injury.
7. cIAIs with a low risk of complications who may receive more than 72 hours antibiotics are not intended to be included, such as those listed above. Clinician assessment on the eligibility of patients receiving more than 72 hours of in-patient surgical care and antibiotics for their cIAI may be required in patients who have clinically improved at this point and do not require active surgical care but remain in hospital and on antibiotics.
8. Current enrolment in another trial dictating antibiotic treatment duration.
9. Previous Clostridium difficile infection
10. Infected necrotic pancreatitis
11. Concomitant infection requiring ≥4 weeks antibiotic therapy including Intra-hepatic abscess

/es planned to be treated with fixed-extended-duration antibiotics of 4 to 6 weeks antibiotics, osteomyelitis, and endocarditis.
12. Peritoneal dialysis
13. Previously recruited for the EXTEND trial
14. cIAI with an antimicrobially resistant infection without a safe (non-toxic) and effective antibiotic treatment option
15. Treatment with Interleukin-6 Inhibitors
16. High likelihood of death within 72 hours of cIAI randomisation in the opinion of the local Investigator or limitations in treatment decided before inclusion
17. Patient with persistent cIAI of more than 6 months duration

Date of first enrolment
01/09/2022

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
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LS9 7TF

Study participating centre
East Cheshire NHS Trust
Macclesfield District Hospital
Victoria Road
Macclesfield
England
SK10 3BL

Study participating centre

Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro
England
TR1 3LJ

Study participating centre
University Hospital Coventry & Warwickshire
Clifford Bridge Road
Walsgrave
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CV2 2DX

Study participating centre
County Durham and Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
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DL3 6HX

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
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PR2 9HT

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
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LE1 5WW

Study participating centre

Manchester University NHS Foundation Trust
Manchester Royal Infirmary
Oxford Road
Manchester
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M13 9WL

Study participating centre
North Bristol NHS Trust
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Southmead Road
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BS10 5NB

Study participating centre
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Northern General Hospital
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249 Westminster Bridge Road
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University Hospitals Sussex NHS Foundation Trust
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Eastern Road
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BN2 5BE

Study participating centre

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TN37 7RD

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Study participating centre
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Study participating centre

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Study participating centre
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Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Protocol (other)		23/05/2022	12/11/2026	No	No
Study website		11/11/2025	11/11/2025	No	Yes