ISRCTN71978064 https://doi.org/10.1186/ISRCTN71978064

A trial evaluating active outpatient management to prevent hospital admission in women having fertility treatment who develop ovarian hyperstimulation syndrome

Submission date
03/03/2022

Recruitment status
No longer recruiting

Registration date
07/03/2022

Overall study status
Stopped

Last Edited
19/09/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Ovarian hyperstimulation syndrome (OHSS) is a condition that can affect women undergoing fertility treatment. OHSS is caused by the medication taken to increase egg production during ovulation induction or in vitro fertilisation (IVF). If too many eggs develop, the ovaries can become large and painful. It can affect women who are recovering from the effects of the medication given during their fertility treatment, and those who have become pregnant after treatment. Symptoms are often more severe in pregnant women.
OHSS can range in severity and can be categorised as mild, moderate or severe. Mild symptoms are common, whereby the woman feels unwell and experiences shortness of breath, abdominal pain and bloating. This is usually resolved quickly, but for 3-8% of women undergoing IVF, these symptoms can worsen to moderate or severe OHSS. Severe OHSS can lead to serious health complications needing treatment in hospital for several days or weeks, and in a small number of women can be life-threatening.
Current management of OHSS is conservative; fertility teams monitor the condition, and if severe symptoms develop the woman is admitted to hospital for intensive monitoring and/or treatment. This treatment can include a procedure called paracentesis, which involves a needle being inserted through the vagina or abdomen to drain the fluid that has collected to relieve the OHSS symptoms. Paracentesis is normally performed in an inpatient setting.
The aim of this study is to understand whether carrying out the same paracentesis procedure but early and as an outpatient (and including additional monitoring) can stop OHSS symptoms from worsening, and can prevent women from having to be admitted to hospital.

Who can participate?
Women with moderate or severe (early or late) OHSS

What does the study involve?
Women deemed at risk of OHSS will be informed about the study and monitored. If OHSS develops, they will be asked to take part in the study. If they agree, a computer will randomly

determine whether they receive either outpatient paracentesis or usual care. The women will be followed up to see how quickly their symptoms resolve and whether hospital admission is needed. The researchers will also compare the safety, acceptability and cost of the treatment. They will primarily be looking at any OHSS-related hospital admissions of at least 24 hours, within 28 days of randomisation. This information will be collected by staff at fertility units by contacting the participant by telephone, at patient visits, or from hospital notes after 28 days. Participants will then be followed up at 90 days to review medical notes and collect data on thrombosis or embolism, significant infections, hospitalisations and pregnancy. If pregnant at 90 days, they will be followed up again at 13.5 months to review the medical notes and collect data on live birth information, pregnancy outcomes, death and serious adverse events for the baby.

What are the possible benefits and risks of participating?
Taking part in this study may or may not reduce a participant's chances of going into hospital because of OHSS, but information from this trial may help doctors understand whether it would be helpful to offer this outpatient procedure to women who have moderate or severe OHSS in the future.
Paracentesis is a relatively safe procedure. Paracentesis is already regularly carried out at many hospitals for patients who are admitted for treatment. Potential complications include feeling tired, dizzy or lightheaded, increased pain in the tummy, low blood pressure or bleeding from the drainage site but these are short-term symptoms and will be managed by the clinical team during the procedure. There is also the possibility of infection and injury to major blood vessels or bowel, but these are extremely rare. In this study the procedure will be performed by the doctor/nurse/radiologist in an outpatient setting to prevent the OHSS symptoms from getting worse. It can feel uncomfortable like egg collection, but pain relief will be given. Additionally, completing the patient diary daily for 28 days may be an inconvenience. This includes measurements of weight, abdominal girth, fluid intake and urine output. For patients in the intervention group, the study will use this information to monitor participants' condition.

Where is the study run from?
The University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
December 2019 to March 2024

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) (UK)

Who is the main contact?
Katie Ridsdale, k.ridsdale@sheffield.ac.uk

Study website
https://www.sheffield.ac.uk/scharr/research/centres/ctru/stop-ohss

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
298619

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51579, IRAS 298619

Study information

Scientific Title
STOP-OHSS (Shaping and Trialling Outpatient Protocols for Ovarian HyperStimulation Syndrome): A randomised controlled trial to assess the clinical and cost-effectiveness of active management of ovarian hyperstimulation syndrome.

Acronym
STOP-OHSS

Study objectives
The use of outpatient paracentesis (OP) in the management of moderate or severe OHSS will result in earlier resolution of symptoms and avoid the need for hospital admission, when compared with usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/02/2022, London - South East Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8085, +44 (0)207 104 8104, +44 (0)207 104 8265; londonsoutheast.rec@hra.nhs.uk), REC ref: 22/LO/0015

Study design
Randomized; Both; Design type: Treatment, Surgery, Qualitative

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
Ovarian hyperstimulation syndrome

Interventions
Design:
A randomised controlled trial (RCT) to assess the clinical and cost-effectiveness, safety profile and acceptability of outpatient paracentesis compared to conventional conservative management (usual care) of women with moderate or severe OHSS

Hypothesis:
The use of outpatient paracentesis (OP) in the management of moderate or severe OHSS will result in earlier resolution of symptoms and avoid the need for hospital admission, when compared with usual care.

Recruitment:
This RCT will recruit women with early or late moderate or severe OHSS from approximately 20 NHS and private fertility units across England and Scotland. Women with a diagnosis of moderate or severe OHSS who meet the inclusion criteria will be randomly allocated (1:1) to either the treatment arm (where they will receive outpatient paracentesis and increased monitoring) or the control arm (where they will receive conservative management, which at most sites is usual care).

A ‘conservative management’ (usual care) control arm has been selected in order to ascertain if outpatient paracentesis and increased monitoring is more effective than ‘conservative management’ (usual care) at reducing hospitalisations.

Following ethical approval, the research will be undertaken as detailed below.
1. Local site confirmation of capacity and capability and site set-up
2. Participant recruitment, baseline data collection, randomisation and intervention delivery will begin.
3. An internal pilot will take place for the first 15 months of recruitment. This internal pilot will assess the feasibility aspects relating to rates of recruitment, retention of randomised participants and intervention delivery. If the internal pilot progression criteria are met the study will continue into the next phase. Qualitative research (including interviews) will be conducted within the internal pilot phase in order to identify and resolve any issues with the conduct of the RCT.
4. Participant recruitment, baseline data collection, randomisation and intervention delivery for the main trial will continue if the progression criteria are met.
5. An interim analysis will be performed for futility early stopping when 65% (73 per arm) of the maximum required participants have accrued primary outcome data on hospitalisation. Early stopping for efficacy is not permitted.
6. Participant follow-up undertaken. All participants will complete a daily diary of their

symptoms for 28 days after randomisation or until symptom resolution. They will also have weekly follow up appointments (either face to face or remotely) up to 28 days after randomisation (or until symptom resolution). They may also attend face to face symptom resolution or deterioration visits.
7. Participant involvement will end at day 28 post-randomisation, but data will be collected from their medical notes 90 days (3 months) after randomisation, those that are identified as pregnant at day 90 will also have their medical notes reviewed at 13.5 months post-randomisation.
8. Data analysis and final report writing

During both the internal pilot and main trial, the patient's journey through the trial will be experienced as follows:
1. Women identified as at risk of developing moderate/severe OHSS, and women who already have mild OHSS will be informed about the study in the following ways:
1.1. Receive a letter of invitation introducing the study (in the post, or by email) with a copy of the brief information leaflet.
1.2. The trial may be introduced and the brief information leaflet provided during a clinic appointment.
1.3. Informed about the trial via the website/recruitment video (based on the participant information sheet) or a poster that will advise patients to discuss the study with their clinician /research nurse documented on the trial delegation log.
2. Women who progress to develop moderate or severe OHSS, and women presenting at fertility centres with moderate or severe OHSS not previously identified as at risk will be approached and provided with the full patient information sheet (PIS) as soon as possible, for example during the clinical appointment arranged to investigate the patient's moderate or severe OHSS symptoms.
3. Eligibility screening will take place when either the woman presents with, or those being monitored progress to, moderate or severe OHSS. Eligibility screening will be based on medical notes and routine clinical investigations already undertaken to confirm the diagnosis of moderate or severe OHSS, and will include ultrasound scans to confirm the presence of ascites.
4. Once consented to participate, the eligible participant will be randomised to either the intervention or control arm of the study.
4.1. Women who are allocated to the intervention arm will be invited to attend an outpatient appointment to have their abdominal fluid drained via paracentesis. The timing of the paracentesis procedure following randomisation for each participant is at the discretion of the local investigator; however they should aim to complete the procedure as soon as clinically possible. Participants will be asked to record self-monitoring information in a daily diary, and will receive training on how to do this. Participants will be provided with a daily diary to record this information and will be asked to report this during monitoring contacts.
4.2. Women who are allocated to the control group will receive usual care at their site. Participants will be asked to record self-monitoring information daily, and will receive training on how to do this. Participants will be provided with a daily diary to record this information.
5. The following information will be collected from contact with the participants/ medical notes throughout the trial:
5.1. Baseline: demographics, contact details, medical history, EQ-5D-5L, weight, size of abdomen, whether they had diarrhoea or vomiting in the past day, pain experienced, shortness of breath experienced, OHSS prevention medication taken, FBC (for haematocrit and white blood cell count)
5.2. Daily patient diary: weight, abdominal girth, diarrhoea and vomiting in past 24 hours, pain, shortness of breath, fluid input and urine output.
5.3. Weekly until symptom resolution (day 7, 14, 21 & 28): Fluid input/output (including vomiting and diarrhoea), abdominal girth, weight, pain, shortness of breath, blood samples (FBC if face to

face appointment), adverse events, details of GnRH antagonist prescription.
5.4. Symptom resolution: Fluid input/output (including vomiting and diarrhoea), abdominal girth, weight, pain, shortness of breath, blood samples (FBC), adverse events, confirmation of symptom resolution form, any OHSS-related hospital admission in 28 days, details of GnRH antagonist prescription. For participants who have received paracentesis, data will be collected on the volume of ascites removed and number of paracentesis performed (if not already collected).
5.5. Symptom deterioration: Fluid input/output (including vomiting and diarrhoea), abdominal girth, weight, pain, shortness of breath, blood samples (FBC), adverse events, details of GnRH antagonist prescription. At this visit, the research / clinical team will determine if the participant should be hospitalised and record reasons for this.
5.6. During hospitalisation: Fluid input/ output (including nausea, vomiting & diarrhoea), abdominal girth, weight, pain, shortness of breath. The following information will be collected about hospitalisation from the participant's medical notes: blood test results (FBC), adverse events, location and duration of admission, interventions received (including timing), confirmation of symptom resolution form (if applicable), details of their OHSS treatment including whether they were prescribed GnRH antagonist.
5.7. Day 28: Any OHSS related hospital admissions within 28 days, health resources used, patient cost questionnaire, client satisfaction questionnaire (CSQ-8), EQ-5D-5L, adverse events.
5.8. Day 90: The following information will be collected from medical notes only - occurrence of thrombosis or embolism, significant infections, evidence of an ongoing pregnancy and pregnancy outcome (e.g. miscarriage)
5.9. 13.5 months: For women identified as pregnant at Day 90, the following information will be collected from medical notes only - live birth information, pregnancy outcome (e.g. miscarriage) as well as neonatal death, congenital abnormalities and SAEs for the baby. This data will not be collected for participants recruited in the final 12.5 months of the trial recruitment period.

Qualitative study during the internal pilot:
The 15-month internal pilot phase will include a qualitative study which aims to facilitate the feasibility of conducting the RCT by identifying potential problems with recruitment, so that solutions can be instigated rapidly.

The qualitative study will include interviews with women who agree to participate in the trial, women who declined participation and health care professionals involved in recruitment to the STOP-OHSS trial. A sample of recruitment sessions will also be audio recorded (with consent) and reviewed.

Audio recording of 10-12 trial recruitment sessions:
Encrypted audio recorders will be used and prior to the process patients will be given an information sheet with details of how the recording data will be used, and how the data will be stored. Patients will be asked if they consent to the sessions being recorded and asked to sign a consent form to confirm this.

Interviews:
Qualitative semi-structured interviews will be conducted either by telephone, or another remote virtual method, depending on participant preference. The option for a face-to-face interview can also be provided if participants have a strong preference for this and are unlikely to participate otherwise.

Health Care Professionals (HCP):
HCP with recruiting responsibilities at participating centres will be identified by the trial team and approached with information about the study. They will be given a letter introducing the

study and participant information sheet, with the research team contact details. They will be asked to contact the research team if they would like to take part in an interview.

Women who have agreed to participate in the trial:
As part of the consent to participate in the STOP-OHSS trial women with OHSS will be asked to indicate on the consent form if they agree to be contacted by the trial team regarding participation in an interview. The trial team will contact only those women who have consented to contact with information about the interview study. Women will only be contacted about taking part in an interview after they have had their symptom resolution visit, to avoid additional burden whilst they are experiencing symptoms. They will be given a participant information sheet (with researcher contact details), and asked to contact the research team if they would like to take part in an interview.

Women who declined to take part in the trial:
At the point that a woman declines to take part in the trial, the recruiting HCP will give a brief explanation about the interview study and they will be given an information pack containing a letter introducing the study, a participant information sheet (with researcher team contact details). They will be asked to contact the research team if they would like to participate in an interview. We will take care when approaching women who have declined to participate in the RCT to ensure they understand that we are not trying to change their minds and respect their decision.

Consent:
Written informed consent will be obtained from all participants in the form of an electronic consent form sent prior to the interview. If participants do not have an email address to be able to access the consent form then audio consent will be taken at the start of the interview and recorded, and the researcher will complete the consent form on their behalf.

All interviews and a sample of recruitment sessions will be audio-recorded and transcribed. The Data Monitoring and Ethics Committee (DMEC) and Trial Steering Committee (TSC) will monitor Serious Adverse Events throughout the trial in addition to monitoring and advising on the progress of the trial.

Intervention Type
Procedure/Surgery

Primary outcome measure
OHSS-related hospitalisation for at least 24 hours measured using data collected by staff at fertility units by contacting the participant by telephone during monitoring, at patient visits within 28 days of randomisation or collected from hospital notes after 28 days

Secondary outcome measures
Current secondary outcome measures as of was changed from ISRCTN71978064 .

1. Need for hospitalisation (OHSS related) measured using data collected during symptom deterioration visits or other routes of hospitalisation, including clinical data and reasons stated for hospitalisation within 28 days of randomisation – independent blinded central assessment
2. Cumulative length of OHSS related hospitalisation - providing a measure of the total burden of hospital stay assessed within 28 days post-randomisation, including any admissions for short periods that may not have met the primary outcome.
3. Time to resolution of OHSS measured using normalisation of the haematocrit and

haemoglobin concentrations, normalisation of fluid input and output (no longer in a positive fluid balance), decrease in weight, and decrease in abdominal girth within 28 days of randomisation
4. Progression of OHSS severity measured using the following criteria:
4.1. Progression criteria from moderate to severe indicated by fluid accumulation in abdomen which becomes clinical ascites/clinically detectable with or with hydrothorax, with any of the following additional symptoms:
4.1.1. Clinical ascites (± hydrothorax)
4.1.2. Oliguria (< 300 ml/day or <30 ml/hour)
4.1.3. Haematocrit >0.45
4.1.4. Hyponatraemia (sodium <135 mmol/l)
4.1.5. Hypo-osmolality (osmolality <282 mOsm/kg)
4.1.6. Hyperkalaemia (potassium >5 mmol/l)
4.1.7. Hypoproteinaemia (serum albumin <35 g/l)
4.1.8. Ovarian size usually >12 cm
4.2. Progression criteria from severe to critical indicated by evidence of any one of the following features:
4.2.1. Participant has a large hydrothorax
4.2.2. Increasing haematocrit levels to >0.55
4.2.3. A white cell count of over 25000/ml (confirmed via FBC test)
4.2.4. Change from oliguria (low urine output) to anuria (very little/no urine) (<100 ml/day)
4.2.5. Thromboembolism
4.2.6. Acute respiratory distress syndrome
1. within 28 days of randomisation
5. Live birth, pregnancy outcomes, neonatal death and serious adverse events including congenital abnormalities in the newborn measured using medical notes within 13.5 months of randomisation
6. The occurrence of thrombosis or embolism and significant infections requiring antibiotic treatment or hospitalisation measured using medical notes within 90 days of randomisation
7. Adverse events measured using medical notes, during a follow-up, during contact with the participant, or during site monitoring within 28 days of randomisation. Specified adverse events will be identified through review of medical notes at 90 days and 13.5 months post randomisation
8. Patient satisfaction assessed using the Client Satisfaction Questionnaire 8 (CSQ-8) based on total scores at 28 days post-randomisation
9. Quality of life measured using EQ-5D-5L daily and at 28 days post-randomisation

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Previous secondary outcome measures:

1. Need for hospitalisation (OHSS related) measured using data collected during symptom deterioration visits or other routes of hospitalisation, including clinical data and reasons stated for hospitalisation within 28 days of randomisation – independent blinded central assessment
2. Time to resolution of OHSS measured using normalisation of the haematocrit and haemoglobin concentrations, normalisation of fluid input and output (no longer in a positive fluid balance), decrease in weight, and decrease in abdominal girth within 28 days of randomisation
3. Progression of OHSS severity measured using the following criteria:
3.1. Progression criteria from moderate to severe indicated by fluid accumulation in abdomen which becomes clinical ascites/clinically detectable with or with hydrothorax, with any of the following additional symptoms:

3.1.1. Clinical ascites (± hydrothorax)
3.1.2. Oliguria (< 300 ml/day or <30 ml/hour)
3.1.3. Haematocrit >0.45
3.1.4. Hyponatraemia (sodium <135 mmol/l)
3.1.5. Hypo-osmolality (osmolality <282 mOsm/kg)
3.1.6. Hyperkalaemia (potassium >5 mmol/l)
3.1.7. Hypoproteinaemia (serum albumin <35 g/l)
3.1.8. Ovarian size usually >12 cm
3.2. Progression criteria from severe to critical indicated by evidence of any one of the following features:
3.2.1. Participant has a large hydrothorax
3.2.2. Increasing haematocrit levels to >0.55
3.2.3. A white cell count of over 25000/ml (confirmed via FBC test)
3.2.4. Change from oliguria (low urine output) to anuria (very little/no urine) (<100 ml/day)
3.2.5. Thromboembolism
3.2.6. Acute respiratory distress syndrome
within 28 days of randomisation
4. Live birth, pregnancy outcomes, neonatal death and serious adverse events including congenital abnormalities in the newborn measured using medical notes within 13.5 months of randomisation
5. The occurrence of thrombosis or embolism and significant infections requiring antibiotic treatment or hospitalisation measured using medical notes within 90 days of randomisation
6. Adverse events measured using medical notes, during a follow-up, during contact with the participant, or during site monitoring within 28 days of randomisation. Specified adverse events will be identified through review of medical notes at 90 days and 13.5 months post randomisation
7. Patient satisfaction assessed using the Client Satisfaction Questionnaire 8 (CSQ-8) based on total scores at 28 days post-randomisation
8. Quality of life measured using EQ-5D-5L daily and at 28 days post-randomisation

Overall study start date
01/12/2019

Completion date
31/03/2024

Reason abandoned (if study stopped)
The study was closed by the NIHR Reset Research programme

Eligibility

Key inclusion criteria
1. Women presenting with moderate or severe, early or late OHSS as defined by the trial (see trial protocol for full definitions)
2. Patients able and willing to attend weekly follow-up appointments in person or remotely, daily remote appointments/phone calls, and able to undertake self-monitoring at home

Participant type(s)
Patient

Age group

Adult

Sex
Female

Target number of participants
Planned Sample Size: 224; UK Sample Size: 224

Total final enrolment
8

Key exclusion criteria
1. OHSS-related exclusion criteria:
1.1. Significant pain* or vomiting requiring hospitalisation
1.2. Pulmonary embolism
1.3. When in the judgment of the clinician, the patient's condition is severe enough to warrant admission to a High Dependency Care Unit (such as Critical OHSS as defined in the Royal College of Obstetricians and Gynaecologists (RCOG) green-top guidelines) and therefore not suitable for outpatient management
2. Non-OHSS related medical conditions: a concurrent medical condition requiring immediate inpatient management
3. Patients who have been previously randomised but later present with moderate or severe OHSS symptoms in subsequent cycles after their initial trial involvement
4. Participation in other trials involving ovarian stimulation or ovarian response

*Significant pain will require clinical judgement but may be guided by whether the patient is able to cope at home using 'over the counter' analgesia or if there are any clinical concerns regarding other conditions potentially contributing to the pain (e.g. ectopic pregnancy)

Date of first enrolment
21/03/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Aberdeen Maternity Hospital
Foresterhill

Aberdeen
United Kingdom
AB25 2ZL

Study participating centre
University Hospital Coventry
Centre for Reproductive Medicine
University Hospitals Coventry and Warwickshire NHS Trust
45 Farber Road
Coventry
United Kingdom
CV2 2BH

Study participating centre
Queen Elizabeth Hospital Gateshead
Gateshead Fertility Unit
Queen Elizabeth Avenue
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Liverpool Womens Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

Study participating centre
St Mary's Hospital
Department of Reproductive Medicine
Central Manchester University NHS Foundation Trust
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Jessop Wing
Tree Root Walk
Sheffield

United Kingdom
S10 2SF

Study participating centre
Guys Hospital
Guys Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
University Hospital of Hartlepool
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

Study participating centre
Hammersmith Hospital
Du Cane Road
Hammersmith
London
United Kingdom
W12 0HS

Study participating centre
The Newcastle Fertility Centre
International Centre for Life
Central Parkway
Newcastle upon Tyne
United Kingdom
NE1 3BZ

Study participating centre
Complete Fertility Ltd (southampton)
Princess Anne Hospital
Level G, Mailpoint 105
Coxford Road

Southampton
United Kingdom
SO16 5YA

Study participating centre
University College Hospital
Reproductive Medicine Unit
University College London Hospitals NHS Foundation Trust
235 Euston Road
Bloomsbury
London
United Kingdom
NW1 2BU

Study participating centre
Glasgow Royal Infirmary
Academic Unit of Reproductive and Maternal Medicine
NHS Greater Glasgow and Clyde
University of Glasgow
10-16 Alexandra Parade
Glasgow
United Kingdom
G31 2ER

Study participating centre
Herts & Essex Fertility Centre - Bishops College
Bishops College
Churchgate
Cheshunt
Waltham Cross
United Kingdom
EN8 9XP

Study participating centre
Ivf London (caspian House)
Caspian House
The Waterfront
Elstree Road
Borehamwood
United Kingdom
WD6 3BS

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

Sponsor details
c/o Dipak Patel
Clinical Research & Innovation Office, D49, D Floor
Royal Hallamshire Hospital
Glossop Road
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United Kingdom
S10 2JF
+44 (0)114 226 5941
dipak.patel12@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.sth.nhs.uk/

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR128137

Results and Publications

Publication and dissemination plan
The results of the study will be disseminated through peer-reviewed scientific journals and at clinical and academic conferences, as well as submission of a final report to the funder, which will be made available online. Details of the study will also be made available on the Sheffield CTRU website. Summaries of the research will be updated periodically to inform readers of

ongoing progress. Full details of publications and dissemination to participants, healthcare professionals and the public, including guidance on authorship, are documented in a publication and dissemination plan.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
Deidentified participant data and statistical code will be made available upon reasonable request. Requests should be made via email to ctru@sheffield.ac.uk, stating the data fields required and purpose of the request (ideally with a protocol but, at a minimum, with a research plan). The data dictionary and statistical analysis plan can also be made available. Requests will be considered on a case-by-case basis and requestors will be asked to complete a data sharing agreement with the sponsor before data transfer.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	02/02/2022	03/03/2022	No	No
Protocol file	version 4	12/01/2023	06/06/2023	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 5	21/03/2023	28/11/2023	No	No
Protocol article		22/01/2024	24/01/2024	Yes	No
Basic results		19/09/2024	19/09/2024	No	No