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# Informing the design of a clinical trial into umbilical hernia repair

**Submission date**
28/03/2025

**Recruitment status**
Recruiting

**Registration date**
30/06/2025

**Overall study status**
Ongoing

**Last Edited**
30/06/2025

**Condition category**
Surgery

[ ] 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
Umbilical hernia is a swelling at the belly button. This can contain fat or sometimes parts of the bowel. Around 2,700 people in England need an emergency operation each year for a hernia that has become stuck and painful. There is debate among surgeons on the best way to fix a hernia, so we need a trial to find the best method. However, there are some questions around how long it would take to find the patients for a trial, and whether surgeons would agree to use different ways to fix a hernia. We aim to recruit 50-100 patients from several hospitals to our study to help us answer these questions. The study will not change care in itself, but will help us design the planned trial.

Who can participate?
Patients aged 18 years and over who are having an emergency operation to fix their umbilical hernia

What does the study involve?
We will ask participants to tell us about their quality of life and hernia symptoms before surgery (two questionnaires). Following surgery, we will contact participants by email to complete those questionnaires on quality of life and hernia symptoms again and tell us about their wound health (three questionnaires). This will be at 7 and 30 days post-surgery. We will also collect some clinical details about their hernia and the operation to repair it.
Participation will not change how their umbilical hernia is treated. The surgeon operating will use their standard practice to repair the hernia.
After the operation, we will conduct a theoretical exercise with the surgeon. We will randomly pick a repair method and ask the surgeon if they would have performed the hernia repair using it. We will also randomly allocate whether the patient would have received post-operative antibiotics and ask the surgeon if they would accept this treatment allocation. This exercise will help us understand if there are any barriers to surgeons taking part in the full study.

What are the possible benefits and risks of participating?
There are no direct benefits for participants, but it will help us to confirm how long it would take to deliver a trial, how many participants we might not get longer-term outcomes for, and whether surgeons will accept randomisation. This may benefit future patients with umbilical

hernias get better treatment.
There are no clinical risks to participating, as there are no changes to patient care.

Where is the study run from?
The study is being run by the Birmingham Centre for Observational and Prospective Studies (BiCOPS), part of the University of Birmingham. The lead NHS site is the Queen Elizabeth Hospital, Birmingham, part of University Hospitals Birmingham NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
March 2025 to June 2026

Who is the study funded by?
The British Hernia Society (UK)

Who is the main contact?
Dr Michala Pettitt, bhamred@contacts.bham.ac.uk

# Contact information

### Type(s)

### Contact name
Dr Michala Pettitt

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
343722

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 66875

# Study information

### Scientific Title
Assessment of Surgeon Treatment Equipoise & Randomisation Opinion to Inform trial Design (ASTEROID)

### Acronym
ASTEROID

### Study objectives
ASTEROID is a feasibility study to inform the design of a subsequent RCT and has the recruitment rate of patients undergoing emergency repair of their umbilical hernia as its primary outcome. Secondary outcomes include the willingness of these patients to complete patient-reported outcome measures at 7 and 30 days post-surgery to measure patient retention rates, and the equipoise of surgeons to randomise between different repair types and antibiotic regimen post-surgery.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 07/03/2025, London – West London & GTAC Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8098, +44 (0)2071048075; westlondon.rec@hra.nhs.uk), ref: 24/PR/1597

### Study design
Observational cohort study

### Primary study design
Observational

### Secondary study design
Cohort study

### 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
Surgery

### Interventions
Potential participants will attend hospital with an umbilical hernia which is either stuck (non-reducible), is causing bowel blockage (obstructed), or has lost blood supply to its contents

(strangulated). They will be booked for an operation by the surgical team. This operation can take place anywhere from immediately to up to a day later, depending on symptoms and competing system pressures.

The clinical team will assess patient eligibility and make an initial approach to the patient, outlining study participation. If the patient is interested in discussing the study, the clinical team will introduce the potential participant to the research team who will provide the patient with a patient information sheet and explain the study, highlighting that it will not change their care.

The patient will be allowed a period of time to consider participation. After an appropriate period, the research team will return and discuss the study with the patient, answering any questions they may have. If the patient declines participation, relevant information will be recorded on the screening log. If they wish to participate, they will complete a consent form. An email address will be collected for follow-up questionnaires.

Following this, the participant will complete two questionnaires, the EQ-5D-5L (generic quality of life) and the Abdominal Hernia Questionnaire (preoperative version).

The participant will undergo clinical care as routine, including surgery and hospital discharge.

Follow-up questionnaires will be triggered by the central database, and links with reminders to complete will be sent at post-operative day 7 (+/- 2 days), and post-operative day 30 (+/- 7 days). The participant will be asked to complete the EQ-5D-5L a, the Abdominal Hernia Questionnaire (post-operative version), and the Bluebelle wound health questionnaire at each time point.

Any reattendance at hospital for readmission, hernia recurrence, or reoperation within 30 days will be noted by the clinical team.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Time to recruit patients, measured as the number of patients consented into ASTEROID per centre per month

### Secondary outcome measures
1. The proportion of patients retained in the study at 30 days post-surgery will be derived from the number of fully completed PROMs at the 30-day timepoint / the number of patients consented at baseline
2. The proportion of surgeons willing to randomise the patient for repair type and post-surgical antibiotics will be assessed as those willing to accept the theoretical randomised allocations over those who would not, measured at baseline
3. Reoperation on hernia within 30 days, collected as a specific variable on the 30-day follow-up form
4. Surgical site infection within 30 days (defined using CDC criteria)
5. Surgical site occurrence within 30 days (defined as surgical site infection OR seroma [clinical /radiological] OR wound dehiscence)

**Overall study start date**
07/03/2025

**Completion date**
30/06/2026

# Eligibility

**Key inclusion criteria**
Adult patients undergoing emergency open repair of a strangulated, incarcerated, or obstructed umbilical hernia

**Participant type(s)**
Patient

**Age group**
Adult

**Sex**
Both

**Target number of participants**
Planned Sample Size: 100; UK Sample Size: 100

**Key exclusion criteria**
1. Patients who are pregnant will not be eligible as they have altered abdominal wall biomechanics
2. Patients with cirrhosis will not be eligible due to different disease processes driving outcomes

**Date of first enrolment**
01/05/2025

**Date of final enrolment**
30/04/2026

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Queen Elizabeth Hospital**
Mindelson Way
Birmingham
United Kingdom
B15 2GW

# Sponsor information

### Organisation
University of Birmingham

### Sponsor details
Edgbaston
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### Sponsor type
University/education

### Website
http://www.birmingham.ac.uk/index.aspx

### ROR
https://ror.org/03angcq70

# Funder(s)

### Funder type
Charity

### Funder Name
British Hernia Society

# Results and Publications

### Publication and dissemination plan
ASTEROID will be published in a high-impact peer-reviewed journal, using the corporate authorship model, with the aim of the results being in the public domain within 12 months of the completion of the study.

### Intention to publish date
30/06/2027

## Individual participant data (IPD) sharing plan

Requests for data generated during this study will be considered by the BiCOPS team. Data will typically be available after the primary publication of ASTEROID. Only scientifically sound proposals from appropriately qualified research groups will be considered for data sharing. The request will be reviewed by the BiCOPS team in discussion with the CI and, where appropriate (or in the absence of the CI), any of the following: the Study Sponsor or the SMG. A formal Data Sharing Agreement (DSA) may be required between respective organisations once the release of the data is approved and before data can be released. Data will be fully de-identified (anonymised). Applications should be made to bicops@contacts.bham.ac.uk.

## IPD sharing plan summary

Available on request, Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Other files | Study schema | | 07/04/2025 | No | No |
| Participant information sheet | version 1.1 | 28/02/2025 | 07/04/2025 | No | Yes |