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Duramesh versus suture for prevention of port-site hernia after keyhole surgery

Submission date 10/04/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/04/2025	**Overall study status** Ongoing	
Last Edited 09/05/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
At the end of a keyhole operation, the strength-bearing layer around the abdominal muscles, called "fascia", needs to be closed to prevent hernias from occurring. This is typically performed with sutures. Even when closed with sutures, the best available evidence suggests that the rate of "port-site hernia" is ~25%. This research aims to investigate if a new product called "Duramesh" is better than standard suture for reducing the rate of port-site hernia after keyhole surgery.

Who can participate?
Adult patients who are undergoing keyhole surgery in the NHS.

What does the study involve?
Half of the patients will receive Duramesh (intervention group), and half will receive standard suture (control group). Patients will be randomly allocated to one of the groups and will not know which closure technique they will receive. People measuring the outcome are also blinded to which treatment participants receive (double-blind). Other than the closure method, the operation that participants receive will not be any different from if they were not part of this trial. Participants will be followed up after their keyhole operation at 3 months, 1 year and 2 years. At each of the timepoints, an ultrasound scan of the umbilical region will be performed to look for port-site hernia. Other outcome measures include wound events, re-operation, length of hospital stay and postoperative quality of life.

What are the possible benefits and risks of participating?
In terms of benefit, Duramesh may reduce patients' risk of developing a port-site hernia within 2 years and possibly beyond that timeframe, too. This may prevent patients from requiring another operation in the future, some of which may be an emergency with incarcerated or strangulated bowel. In terms of possible risk, Duramesh is non-absorbable, similar to most modern synthetic hernia meshes. It will therefore remain intact for the rest of the patient's life. It is not known how this affects a patient's chance of getting complications, but the type of complications is similar to standard surgical suture. Having Duramesh does not affect a patient's ability to have surgery in the future.

Where is the study run from?
Croydon University Hospital, London, UK.

When is the study starting and how long is it expected to run for?
October 2024 to December 2028. The study will start recruiting in June 2025. It is expected to run for 3.5 years in total: 1.5 years for recruitment and 2 years for follow-up.

Who is funding the study?
Eurosurgical Ltd.

Who is the main contact?
TROCAR trial coordinator, ch-tr.trocartrial@nhs.net

Contact information

Type(s)
Principal Investigator

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
350452

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 65163

Study information

Scientific Title
A prospective single-centre double-blind randomised controlled trial of Duramesh versus conventional suture closure for laparoscopic periumbilical trocar sites

Acronym
TROCAR

Study objectives
The principal aim is to determine if Duramesh is superior to standard suture closure for reducing rates of trocar-site hernia following laparoscopic surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/04/2025, East of England, Cambridge Central REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048089; cambridgecentral.rec@hra.nhs.uk), ref: 25/EE/0057

Study design
Single-centre parallel-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Duramesh versus conventional suture closure for laparoscopic periumbilical trocar sites

Interventions
TROCAR is a single-centre, parallel arm, randomised controlled trial of Duramesh versus conventional suture, with blinding of patients and outcome assessors at primary outcome assessment. The aim is to establish if Duramesh is superior to conventional suture for the prevention of trocar-site hernia at 2 years when closing periumbilical trocar sites greater than or equal to 10mm. A total of 250 participants undergoing laparoscopic surgery will be randomly allocated (randomisation ratio 1:1 and computer-generated sequence block size 4) to one of the two groups and followed up for 2 years. Patients will attend follow-up appointments at Croydon University Hospital at 3 months, 1 year and 2 years after the index operation.

The primary outcome is the cumulative incidence of trocar-site hernia at 2 years. Secondary outcomes include 90-day occurrence of wound events, reoperation, and mortality, and patient-reported quality of life at 3 months, 1 year and 2 years. An ultrasound scan of the periumbilical region will be performed to look for trocar-site hernia at each of the timepoints.

Intervention Type
Procedure/Surgery

Primary outcome measure
The cumulative occurrence of trocar-site hernia over 2 years, measured using ultrasound scan at 3 months, 1 year and 2 years

Secondary outcome measures
1. Surgical site occurrence within 90 days measured using physical examination
2. Reoperation within 90 days measured using data collected from patient medical records at one timepoint
3. Mortality within 90 days measured using data collected from patient medical records at one timepoint
4. Length of hospital stay in days measured using data collected from patient medical records at one timepoint
5. Patient reported quality of life (QoL) measured using the Modified EuraHS-QoL score and Modified Carolinas Comfort Scale at 3 months, 1 year and 2 years

Overall study start date
01/10/2024

Completion date
09/12/2028

Eligibility

Key inclusion criteria
1. 18 years or older.
2. Able to provide written informed consent to participation, without barriers that might

prevent follow-up.
3. Any laparoscopic procedure pertaining to the domain of general surgery, requiring periumbilical incision at the linea alba for trocar insertion 10mm or greater.
4. Extraction sites acceptable up to a maximum of 3cm.
5. Concurrent umbilical hernia if camera port inserted through the defect with subsequent primary repair without planar mesh.
6. Hernia at a remote site from port incisions e.g. concurrent inguinal hernia.
7. Previous abdominal surgery, except for the condition specified in exclusion criteria below.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 250; UK Sample Size: 250

Key exclusion criteria
1. Lack of capacity to consent to trial participation.
2. Procedures where placement of a periumbilical trocar <10mm is planned.
3. Periumbilical trocar insertion not planned or not possible.
4. Laparoscopic gynaecological procedures.
5. Laparoscopic urological procedures.
6. Single-incision laparoscopic surgery.
7. Unanticipated conversion to laparotomy or specimen extraction site at the umbilicus exceeds 3cm.
8. Use of planar mesh or previous planar mesh covering the periumbilical trocar site.
9. Concurrent umbilical hernia not primarily repaired during trial procedure.
10. Previous abdominal surgery, if in the opinion of the principal investigator, is not suitable for inclusion e.g. battlefield abdomen, enterocutaneous fistulae, multiple previous laparotomies etc.
11. Pregnancy.
12. BMI > 40.

Date of first enrolment
09/06/2025

Date of final enrolment
09/12/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Croydon University Hospital
London Road
Croydon
United Kingdom
CR7 7YE

Sponsor information

Organisation
Croydon Health Services NHS Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.croydonhealthservices.nhs.uk/

ROR
https://ror.org/00sh7p618

Funder(s)

Funder type
Industry

Funder Name
Eurosurgical Limited

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/05/2030

Individual participant data (IPD) sharing plan
During the study, research data will not be publicly available and will be stored on Project REDCap hosted by University College London. Upon the end of the study, the full dataset from the REDCap system will be transferred to University College London's Data Safe Haven for archiving.

Data will not be made available for sharing until after the publication of the main results of the study. Contact the TROCAR trial coordinator, ch-tr.trocartrial@nhs.net. Thereafter, pseudonymised patient data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed study has been given a favourable opinion by a Research Ethics Committee.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request