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Comparing three surgical methods to prevent postoperative bulging after open repair of direct groin hernia

Submission date 10/08/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/08/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/08/2026	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

A groin hernia happens when part of the contents of the abdomen pushes through a weak point in the abdominal wall. It is usually repaired with an operation in which a mesh is placed to reinforce the weak area. When the mesh is placed behind the abdominal wall, a thin sheet of tissue that the hernia has stretched over the years is left behind as a slack pouch. Fluid gathers in this pouch after the operation and creates a lump that looks and feels like the hernia has come back. The lump is harmless and disappears on its own, usually within three months, but it worries patients and often leads to extra clinic visits and scans.

Surgeons using keyhole techniques have tried different ways of dealing with this slack tissue, but nobody had tested any of them in the open operation used here. This study compared three approaches to find out whether any of them prevents the lump from forming.

Who can participate?

Men aged 18 years and over with a first-time hernia on one side of the groin, of the type known as a direct hernia, who were due to have a planned repair.

What does the study involve?

All participants had the same operation through a small cut in the groin, with the same type of mesh. They were then placed into one of three groups: in the first group the stretched tissue was left alone, in the second it was cut away, and in the third it was stitched down to a strong ligament underneath. Participants were not put into groups at random; they were assigned in turn according to the order in which they came to the clinic, until each group had 25 people. Everyone was examined 1 week and 1 month after the operation. Those who developed the lump were seen every 2 weeks until it had gone completely.

What are the possible benefits and risks of participating?

The operation, the mesh and the aftercare were the same as those used routinely, and no extra tests were needed. Participants in the second and third groups had one additional step during the operation, adding a stitch or removing a small piece of tissue. There was no way of knowing beforehand which approach, if any, would work better.

Where is the study run from?
Konya City Hospital (Türkiye)

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

Who is funding the study?
Konya City Hospital (Türkiye)

Who is the main contact?
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Study information

Scientific Title
Fixation of the transversalis fascia to Cooper's ligament and pseudohernia after open minimally invasive preperitoneal repair of direct inguinal hernia: a prospective three-arm randomised controlled trial

Study objectives
In open minimally invasive preperitoneal repair of a direct inguinal hernia, the transversalis fascia remains as a lax pouch once the hernia sac has been reduced, and reactive fluid collecting within it produces a pseudohernia. Several intraoperative adjuncts have been described to prevent this after laparoscopic and endoscopic repair, but none has been evaluated for open preperitoneal techniques.

This study tests the hypothesis that manipulating the stretched transversalis fascia during open minimally invasive preperitoneal repair reduces the occurrence of postoperative pseudohernia compared with leaving it untouched. Two manoeuvres are compared with no additional manipulation: excision of the transversalis fascia, and fixation of the transversalis fascia to Cooper's ligament. The study also assesses whether either manoeuvre carries a penalty in terms of pain, haematoma, cord oedema, scrotal oedema or surgical site infection.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/03/2024, Clinical Research Ethics Committee of Selçuk University (Alaeddin Keykubat Campus, Selçuklu, Konya, 42075, Türkiye; +90 (0)332 224 39 63; etikselcuk@gmail.com), ref: 2024/21

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Sequential

Purpose
Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Primary unilateral direct inguinal hernia

Interventions

All participants undergo open minimally invasive preperitoneal repair of a unilateral direct inguinal hernia through a 3–4 cm transverse suprainguinal incision, under spinal anaesthesia unless otherwise indicated. A purpose-made single-layer monofilament polypropylene mesh (38 g/m², trimmed to a 14 × 9 cm oval with four memory-recoil rings of No. 1 polydioxanone suture and a central pocket) is placed in the preperitoneal space, covering the direct, indirect, femoral and obturator orifices. The width of the direct defect is measured after the mesh has been placed. Up to this point the operation is identical in all three arms.

Participants are then allocated to one of three arms:
Arm 1 (control, n = 25): the stretched transversalis fascia is left untouched.
Arm 2 (excision, n = 25): a single polyglactin stitch is passed through the stretched transversalis fascia and tied, and the fascia is then excised.
Arm 3 (fixation, n = 25): the stretched transversalis fascia is retracted and fixed to Cooper's ligament with a polyglactin suture.

The wound is then closed anatomically in all arms. Cefazolin 1 g is given intravenously 30 minutes before incision; intravenous tramadol is given at 0 and 8 hours postoperatively, and at 16 hours if required; a non-steroidal anti-inflammatory drug is prescribed for use as required during the first 10 postoperative days.

Allocation was not randomised. Eligible participants were assigned to the three arms sequentially, in rotation according to the order in which they presented to the outpatient clinic, until each arm contained 25 participants. No random sequence or allocation concealment was used. The protocol approved by the ethics committee had specified allocation by sealed envelope, but this was not implemented in practice.

Participants are assessed at 1 week and 1 month after surgery. Follow-up ends at one month for those without a pseudohernia; those with a pseudohernia are reviewed every two weeks until the collection has regressed completely.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Pseudohernia, defined as a clinically detectable postoperative bulge at the site of the repair, measured using physical examination by the operating surgeon at 1 week after surgery. Ultrasonography was requested only when physical examination was equivocal.

Key secondary outcome(s)
1. Pseudohernia measured using physical examination by the operating surgeon at 1 month after surgery

2. Size of the pseudohernia, measured using the maximum diameter of the palpable collection in centimetres by the operating surgeon at physical examination, at 1 week, at 1 month, and every 2 weeks thereafter until complete regression

3. Time to complete regression of the pseudohernia, measured using the number of months from the date of surgery to the first review at which the collection was no longer detectable on physical examination, with reviews every 2 weeks

4. Pain measured using patient report as present or absent at 1 week and 1 month after surgery

5. Haematoma, cord oedema, scrotal oedema and surgical site infection, each recorded as present or absent, measured using physical examination at 1 week and 1 month after surgery

6. Operating time, measured in minutes from skin incision to completion of wound closure, measured using the operative record at the time of surgery

Completion date
10/12/2024

Eligibility

Key inclusion criteria
1. Male sex
2. Aged 18 years or over
3. Primary unilateral direct inguinal hernia
4. Scheduled for elective repair
5. Written informed consent given

The direct nature of the defect was confirmed intraoperatively

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Male

Total final enrolment
88

Key exclusion criteria
1. Aged under 18 years
2. Female sex
3. Recurrent hernia
4. Bilateral hernia
5. Incarcerated hernia
6. Decompensated systemic disease, such as heart failure, renal failure or chronic obstructive pulmonary disease
7. Comorbidity likely to impair connective tissue integrity or immune competence, such as diabetes mellitus or Ehlers-Danlos syndrome
8. Previous ipsilateral inguinal surgery or previous infraumbilical midline laparotomy
9. Refusal to participate

Date of first enrolment
14/03/2024

Date of final enrolment
10/11/2024

Locations

Countries of recruitment
Türkiye

Sponsor information

Organisation
Konya City Hospital

ROR
https://ror.org/04ze00805

Funder(s)

Funder type

Funder Name
Konya City Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available