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Comparison of mesh fixation techniques in open ventral hernia repair

Submission date	Recruitment status	[ ] Prospectively registered
08/10/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/10/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/08/2024	Surgery	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hernia repair is one of the most common surgeries. The use of mesh in hernia repairs is the method of choice in all postoperative hernias and in primary hernias with a gap larger than 2 cm as it significantly lowers the recurrence rates. The mesh can be placed in various positions in the abdominal wall. In this study the goal is to assess the best fixation method for the mesh: sutures or glue. The fixation method may affect pain and quality of life after surgery, as when glue is used theoretically it does not entrap nerves or puncture vessels that could cause hematoma. The aim of this study is to find whether there is a difference between fixation with sutures or with glue in hernia repair.

Who can participate?
Patients with a ventral hernia are eligible to participate as long as it is safe to undergo surgery according to their health problems.

What does the study involve?
Participants are randomly allocated to undergo hernia repair using sutures or glue.
Questionnaires are completed before the surgery and 1, 3, 6 and 12 months after to see if there is a difference concerning pain, quality of life and other parameters.

What are the possible benefits and risks of participating?
The two fixation methods are already used and are considered safe by the surgical community.
All the data will be collected according to laws and regulations and the identity of the patient will be concealed.

Where is the study run from?
Aristotle University of Thessaloniki

When is the study starting and how long is it expected to run for?
July 2020 to July 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Grigoris Chatzimavroudis
gchatzim@auth.gr

Contact information

Type(s)
Scientific

Contact name
Prof Grigoris Chatzimavroudis

Contact details
2nd Surgical Clinic
Aristotle University of Thessaloniki
G. Gennimatas General Hospital
Ethnikis Aminis 41
Thessaloniki
Greece
54635
+30 (0)2310434680
gchatzim@auth.gr

Additional identifiers

Protocol serial number
36/24-7-20

Study information

Scientific Title
A randomized clinical trial comparing two different mesh fixation techniques in open retromuscular ventral hernia repair

Study objectives
There is a difference between mesh fixation in open retromuscular ventral hernia repair using sutures or glue in terms of early or chronic postoperative pain, quality of life, hernia recurrence or other complications, the duration of the surgical procedure and the length of the hospital stay.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 22/12/2020, The Bioethics Committee of the Aristotle University of Thessaloniki (new building of the medical school, 54124, Thessaloniki, Greece; +30 (0)2310999338; bioethics@med.auth.gr), ref: 3328
2. Approved 06/05/2021, the scientific board of the G. Gennimatas General Hospital of Thessaloniki and the 3rd Health District (Ethnikis Aminis 41, 54635, Thessaloniki, Greece and

Aristotelous 16, 54623, Thessaloniki, Greece; +30 (0)2313305233; education@3ype.gr), ref: Δ3β /19289

Primary study design
Interventional

Study design
Randomized prospective single-blinded clinical single-center study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Retromuscular ventral hernia repair

Interventions
Adults with ventral hernias will be included in this study and they will undergo open ventral hernia repair with retromuscular placement of the mesh. The two techniques that will be applied will be either Rives-Stoppa (for gaps with a transverse diameter of up to 5-6 cm), or posterior separation of the abdominal wall elements with the transversus abdominis release technique (TAR) (for gaps with transverse diameter >5-6 cm). In the field of inguinal hernias, studies have shown that the fixation method may have a difference concerning the postoperative pain and quality of life, when glue is used because theoretically it does not entrap nerves, or punctures vessels that could lead to hematoma. The aim of this study is to expand this observation to the retromuscular ventral hernia repair and find out if this difference applies in this case too. The patients will be randomized with a random number table into two groups based on the fixation method of the mesh (group A: suture, group B: glue). The type of sutures that will be used will be PDS and the glue will be cyanoacrylic, which is a biosynthetic material that is not as studied as the fibrin glue for this procedure.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Postoperative pain measured using the visual analogue scale of pain 0-10 at 3 and 6 months

Key secondary outcome(s)
1. Postoperative pain measured using the visual analogue scale of pain 0-10 at 7, 14, 30 days and 12 months
2. Hernia recurrence measured by clinical examination, CT scan if necessary at 7, 14, 30 days and 12 months
3. Other complications measured by clinical examination, laboratory and radiological tests if necessary at 7, 14, 30 days and 12 months
4. Duration of surgery in minutes, measured after the end of the operation
5. Length of hospital stay in days, measured after the patient’s discharge
6. The amount and the type of analgesic drugs needed at 7, 14, 30 days and 3, 6 and 12 months
7. Quality of life measured using HerQLes and EuraHS QOL preoperatively and at 3, 6 and 12 months. These questionnaires assess the impact of abdominal hernia and surgery on rehabilitation, mental health, daily activities, work, exercise, pain, aesthetic outcome, and sex life.

Completion date
24/07/2023

Eligibility

Key inclusion criteria
1. Adults
2. Ventral hernia
3. Eligible for hernia repair

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
48

Key exclusion criteria
Serious health problems that prevent a safe surgical intervention, for example serious heart or kidney failure

Date of first enrolment
06/05/2021

Date of final enrolment
24/07/2022

Locations

Countries of recruitment
Greece

Study participating centre
Aristotle University of Thessaloniki
2nd Surgical Clinic
G. Gennimatas General Hospital
Ethnikis Aminis 41
Thessaloniki
Greece
54635

Sponsor information

Organisation
Aristotle University of Thessaloniki

ROR
https://ror.org/02j61yw88

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date