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Understanding belly button hernia repair: long-term results and possible complications

Submission date
28/12/2023

Recruitment status
No longer recruiting

Registration date
24/01/2024

Overall study status
Completed

Last Edited
17/12/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Diastasis recti (separation of the muscles along the midline of the abdomen) is a very common condition that can occur in female and male patients, causing functional and appearance-related issues. It happens in 30-70% of people and is sometimes linked with belly button hernias. Lately, doctors have been using a less invasive method involving a mesh repair technique combined with fixing the muscle separation, and it's becoming quite common.

Who can participate?
Patients aged 18 - 70 years, who underwent elective surgery for small and medium size primary umbilical hernia with diastasis recti.

What does the study involve?
We conducted a careful study on people who chose to have surgery for small (< 2 cm) and medium-sized (2-4 cm) umbilical hernias along with muscle separation. We followed them closely for 12 months after the surgery. To check if the hernia came back or if there were fluid collections afterward, we used physical exams and ultrasound. We also measured how much pain they felt using a scale called Visual Analogue Scale (VAS) and looked at their overall comfort and well-being using a questionnaire called Carolinas Comfort Scale (CCS). Additionally, we investigated factors that might independently increase the risk of fluid collections.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Lithuanian hernia society (Lithuania)

When is the study starting and how long is it expected to run for?
September 2020 to December 2022

Who is funding the study?
Lietuvos Sveikatos Mokslų Universitetas (Lithuania)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The risk factors of seromas and long-term results after umbilical hernia with diastasis recti repair using endoscopic subcutaneous approach (SCOLA)

Study objectives
SCOLA procedure is a safe and effective technique for the patients with umbilical hernia and diastasis recti, which gives an acceptable cosmetic results and good quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/09/2020, The Bioethics Centre of the Lithuanian University of Health Sciences (LSMU) (A. Mickeviciaus g. 9, LT-44307 Kaunas, Kaunas, 44307, Lithuania; + 370 37 327 201; bec@lsmu.lt), ref: BEC-MF-04

Study design
Obserevational prospective cohort

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Medical and other records

Study type(s)
Treatment

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Diastasis recti, umbilical hernia

Interventions
A prospective cohort study of patients who underwent elective surgery for small and medium size primary umbilical hernia with diastasis recti was performed.
The institutional review board’s permission no. BEC-MF-04 was obtained prior to this study.
All the patients were examined in the outpatient department 1, 3, 6 and 12 months after surgery.
Patient records were used to gather data.

Intervention Type
Procedure/Surgery

Primary outcome measure

All the patients were examined in the outpatient department 1, 3, 6 and 12 months after surgery:
1. Hernia recurrence and postoperative seromas diagnosis were based on the patient's physical examination and ultrasound, performed by an experienced radiologist.
2. The patient's age, gender, hospital stay, hernia size, postoperative general and wound complications, recurrence rate, postoperative pain were measured using patient records
3. Postoperative pain was evaluated using Visual Analogue Scale (VAS).
4. To evaluate quality of life we used the Carolinas Comfort Scale (CCS) questionnaire: 0 - no symptoms; 1 - mild but not bothersome; 2 - mild and bothersome but not daily; 3 - moderate and /or daily symptoms; 4 - severe symptoms; 5 - disabling symptoms. All the patients were asked to fill the questionnaire 1 week and 1 month after surgery.
5. Umbilical hernias size according to the European Hernia Society (EHS) recommendations: small (<2 cm), medium (2-4cm) and large (>4 cm). Diastasis recti were classified by the new EHS recommendations. Separation between inter-rectus distance: D1 2-3 cm., D2 3-5 cm., and D3 > 5 cm. Type: T1 - after pregnancy or T2 - with adiposity. Concomitant umbilical or epigastric hernia: H0 - without, H1 - present measured using patient records.
6. The risk factors for seromas formation were analyzed: age, gender, diastasis recti size, hernia defect size, surgical repair technique using patient records

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
15/09/2020

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Patients who underwent elective surgery for small and medium size primary umbilical hernia with diastasis recti was performed.
2. Age 18-70 years old.
3. With no other diseases.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
Patiens who had cardiovascular, pulmonary, oncological diseases.

Date of first enrolment
01/01/2019

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Lithuania

Study participating centre
The Hospital of Lithuanian University of Health Sciences Kauno klinikos
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Sponsor information

Organisation
Lithuanian hernia society

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Sponsor type
Research organisation

Website
-

Funder(s)

Funder type
Government

Funder Name
Lietuvos Sveikatos Mokslų Universitetas

Alternative Name(s)
Lithuanian University of Health Sciences, LSMU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Lithuania

Results and Publications

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

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/07/2024	17/12/2024	Yes	No