

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

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| <b>Submission date</b><br>28/12/2023   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>24/01/2024 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>17/12/2024       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> 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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## Contact information

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

Observational prospective cohort

## Primary study design

Observational

## Study type(s)

Treatment

## 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(s)

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

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

70 years

### **Sex**

All

### **Total final enrolment**

100

### **Key exclusion criteria**

Patients 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

Eivenių g. 2, 50161 Kaunas

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Lithuania

50161

# Sponsor information

## Organisation

Lithuanian hernia society

# 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

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 31/07/2024   | 17/12/2024 | Yes            | No              |