

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison the classic surgical cut and the intra-umbilical cut in the umbilical surgeries in terms of cutting length and surgery adverse effects

Protocol summary

Study aim

Comparison the classic surgical cut and the intra-umbilical cut in the umbilical surgeries in terms of cutting length and surgery adverse effects

Design

Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 60 patient with umbilical disorders

Settings and conduct

This study will be conducted with the aim of comparison the classic surgical cut and the intra-umbilical cut in the umbilical surgeries in terms of cutting length and surgery adverse effects in 60 patients with umbilical disorders attending Ali Ebne Abitaleb hospital in Zahedan city. After inclusion in the study, the patients will be assigned into two groups; classic surgical cut group and intra-umbilical cut group. In the classic cut group a 8-12 cm vertical curved incision is given below the umbilicus and the skin and fat tissue is pulled away until the fascia is exposed and the hernia sac is explored and resected and in the intra-umbilical cut group a 6 cm incision is given on the hernia sac in the umbilicus and the skin and fat tissue is pulled away and the hernia sac is freed and resected. After the surgery, the surgical cut size will be measured by a meter in both groups and will be compared together.

Participants/Inclusion and exclusion criteria

Inclusion criterion: having umbilical hernia or other umbilical disorders needing surgery Exclusion criteria: history of umbilical surgery; having underlying diseases such as diabetes

Intervention groups

Classic cut group: a 8-12 cm vertical curved incision is given below the umbilicus and the skin and fat tissue is pulled away until the fascia is exposed and the hernia sac is explored and resected. Intra-umbilical cut group: a 6 cm incision is given on the hernia sac in the umbilicus and the skin and fat tissue is pulled away and the hernia sac is freed and resected.

Main outcome variables

Surgical cut size measured by a meter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210124050125N1**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

Registration date

2021-03-17, 1399/12/27

Registrant information

Name

Alireza Khazaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5715

Email address

dr.khazaei@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-08, 1399/11/20

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the classic surgical cut and the intra-umbilical cut in the umbilical surgeries in terms of cutting length and surgery adverse effects

Public title

Comparison the classic surgical cut and the intra-umbilical cut in the umbilical surgeries in terms of cutting length and surgery adverse effects

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having umbilical hernia or other umbilical disorders needing surgery

Exclusion criteria:

History of umbilical surgery Having underlying diseases such as diabetes

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are randomly assigned into two groups (classic surgical cut group and intra-umbilical cut group) using a random number table. A random number table containing unrepeated numbers between 1 and 60 is selected and the reading is started from the left. If the number is odd the patient is assigned into classic surgical cut group and if the number is even the patient is assigned into intra-umbilical cut group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person analyzing the data won't be aware of the patients assignment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9916789547

Approval date

2021-01-10, 1399/10/21

Ethics committee reference number

IR.ZAUMS.REC.1399.458

Health conditions studied**1****Description of health condition studied**

Umbilical hernia

ICD-10 code

K42

ICD-10 code description

Umbilical hernia

Primary outcomes**1****Description**

Surgical cut size

Timepoint

After the surgery

Method of measurement

By meter

2**Description**

Surgery adverse effects including infection and scarring of the surgery site

Timepoint

Ten days after surgery

Method of measurement

By inspecting the surgery site

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: classic cut group: a 8-12 cm vertical curved incision is given below the umbilicus and the skin and fat tissue is pulled away until the fascia is exposed and the hernia sac is explored and resected.

Category

Treatment - Surgery

2**Description**

Intervention group: intra-umbilical cut group: a 6 cm incision is given on the hernia sac in the umbilicus and the skin and fat tissue is pulled away and the hernia sac is freed and resected.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Ebne Abi Taleb Hospital

Full name of responsible person

Alireza Khazaei

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Khalije Fars Blv, Zahedan

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ayubabedi48@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Taheri

Street address

Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan

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Dr.Taheri@zaums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Alireza Khazaei

Position

General surgery associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

Contact

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General surgery associate professor
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Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable