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
Street address
Khalije Fars Blv, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9916789547
Phone
+98 54 3329 5715
Email
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
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5721
Email
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
Street address
Ali Ebne Abi Taleb Hospital ,Khalije Fars Blv, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5715
Fax
Email
dr.khazaei@zaums.ac.ir

Person responsible for scientific 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
Street address
Ali Ebne Abi Taleb Hospital ,Khalije Fars Blv, Zahedan
City

Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3329 5715

Fax

Email
dr.khazaei@zaums.ac.ir

Person responsible for updating data

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

Street address
Ali Ebne Abi Taleb Hospital ,Khalije Fars Blv, Zahedan

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3329 5715

Fax

Email
dr.khazaei@zaums.ac.ir

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