

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

A comparative Study of Suturing Inguinal Incision with Vicryl and Nylon Threads on the Wound Healing, Cosmetic Results and Surgeon Satisfaction in Children Undergoing Surgery: A Randomized Clinical Trial Study

Protocol summary

Study aim

Comparing the Effect of Suturing the Inguinal Skin Incision with Vicryl and Nylon Sutures in Wound Healing, Cosmetic Results and Surgeon Satisfaction in Children Undergoing Surgery

Design

Clinical trial with two parallel intervention groups, double-blind, randomized, on 56 patients. For simple randomization, lottery and sealed envelopes are used.

Settings and conduct

Candidates for surgery in Bahrami Children's Hospital affiliated to Tehran University of Medical Sciences, with inclusion criteria and informed consent, are assigned to one of the study groups. After the surgery, Inguinal Skin Incision is sutured with either Nylon or Vicryl thread. Surgeon and Technique is the same. After wound dressing, the patient is transferred to the ward. 24 hours later the wound healing questionnaire is completed and also on the third, fifth and seventh days after the operation. On the 15th and 30th day, the scar questionnaire is completed and on the 30th day, surgeon satisfaction is obtained. Data collection is based on operating room, ward and clinic. The participants, the outcome assessor, and the statistical analyst are blinded to the allocation of groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The use of Inguinal Incision for surgery, Clean Wound Classification, age range of 1 to 8 years, Indirect Hernia Type, Hernia Sac Ligation repair method without using Mesh, and the possibility of telephone and in person access after the operation are . Exclusion criteria: also include parents' lack of consent, Congenital Anomalies, Immunodeficiency Diseases, Hematology and Coagulation Diseases and Skin Disorders.

Intervention groups

There are two intervention groups, in one of them, after

the end of the surgery, the Inguinal Skin Incision is sutured with Vicryl thread and in the other group, with Nylon thread.

Main outcome variables

Wound Healing Rate, Scar, Surgeon satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210707051812N1**

Registration date: **2022-12-30, 1401/10/09**

Registration timing: **prospective**

Last update: **2022-12-30, 1401/10/09**

Update count: **0**

Registration date

2022-12-30, 1401/10/09

Registrant information

Name

Jeyran Asadi hajivand

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-31, 1401/10/10

Expected recruitment end date

2023-03-01, 1401/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative Study of Suturing Inguinal Incision with Vicryl and Nylon Threads on the Wound Healing, Cosmetic Results and Surgeon Satisfaction in Children Undergoing Surgery: A Randomized Clinical Trial Study

Public title

Comparing Nylon and Vicryl Threads on Wound Healing, Scar and Surgeon Satisfaction

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Inguinal Incision should be used for surgery The wound should be classified as a Clean Wound The patient's age should be from 1 to 8 years In case of Inguinal Hernia, It should be Indirect Hernia should be repaired by Sac Ligation without using Mesh It should be possible to have In-person and Telephone access with the Patient

Exclusion criteria:

The Patient's Parents do not give Informed Consent Patients having Congenital Anomaly Patients having Immunodeficiency Diseases Patients having Hematology and Coagulation disorders Patients having Skin Disorders

Age

From **1 year** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, Simple Randomization Method and Lottery Type will be used. In this way, a number of folded cards are considered for the Nylon Group and the same number of folded cards are considered for the Vicryl Group. Then the cards are merged and one card is removed and its allocation is recorded. Then the removed card goes back to the cards. Card withdrawal is repeated for the number of samples and a Random Allocation Sequence is obtained. Then each allocation is placed in an Opaque Envelope and the corresponding number is also recorded on the lid of the envelope and arranged in a box according to the sequence. Finally, the

first card is taken for the first patient, the second card is taken for the second patient, and so on until the end.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and their parents are unaware of which group they are in; However, in order to obtain informed consent, full explanations are provided to them. The generation of random allocation is done by a trusted person outside the research team and the box containing the sequence is provided to the surgeon by the principal investigator. One of the surgeons who is a member of the research team is the only person who knows about the allocation of groups because he performs the suturing. The main researcher has the role of evaluating the outcome and is not aware of the allocation of the groups. In addition, the statistician of the group, who has the role of statistical analysis, does not know about the allocation of groups. In addition, the nurses who take care of the patient in the ward will not be informed about the details of the research groups, and the type of thread cannot be recognized from the wound.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Hamadan University of Medical Sciences

Street address

No. 17, Behrouz Mohammadi Alley., Baradaranr Ghaedi Ave

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Province

Tehran

Postal code

1149774611

Approval date

2022-12-04, 1401/09/13

Ethics committee reference number

IR.UMSHA.REC.1401.725

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

Surgical wound healing

ICD-10 code**ICD-10 code description**

2

Description of health condition studied

Surgical Wound Scar

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Wound healing score in REEDA scale

Timepoint

in 24 hours after the operation and on the third, fifth and seventh days after the operation

Method of measurement

REEDA wound healing scale

2

Description

Scar score in Vancouver Scar Scale

Timepoint

15th and 30th day after the operation

Method of measurement

Vancouver Scar Scale

3

Description

Surgeon satisfaction

Timepoint

30th day after the operation

Method of measurement

A 5-point Likert scale developed by the researcher

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: skin suture is performed once at the end of surgery with Vicryl thread. The thread used is VICRYL RAPIDE W9940 type and produced by ETHICON company. It is manufactured by ETHICON, LLC, CE 0086, XZW9940.1 AND LOT number of AK7988. The thread size is 3.0 and the thread length is 75 cm. The thread needle is 26 mm and 3/8 circle and reverse cutting type.

Category

Other

2

Description

Control group: Skin suture is done once at the end of surgery with nylon thread. The thread used is produced by TEB KEYHAN company. It is manufactured by NASG TEB KEYHAN, NO 1467/2, Golchin 2, Golriz 2, West

Ghazali blvd, Eshtehard Industrial, Karaj, Iran. The thread size is 3.0 and the thread length is 75 cm. The thread needle is 26 mm and 3/8 circle and reverse cutting type.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After the publication of the article, confidential information such as the names of individuals and organizations will be removed and other information will be provided to the researchers.

When the data will become available and for how long

Access starts one month after the article is published

To whom data/document is available

All researchers

Under which criteria data/document could be used

In systematic review studies

From where data/document is obtainable

Corresponding author: jeyranasadihajivand@gmail.com

What processes are involved for a request to access data/document

Official and academic email to the corresponding author and obtaining permission from the Research Vice-

Chancellor of Hamadan University of Medical Sciences by the corresponding author
Comments