Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 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

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Name of organization / entity

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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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Tehran
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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
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Sponsors / Funding sources

1

Sponsor
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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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Full name of responsible person

Jeyran Asadi Hajivand

Position

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Latest degree

Bachelor

Other areas of specialty/work

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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