

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of fasciotomy of the testicular tunica albuginea outcomes in treating testicular torsion surgery in children referred to Imam Hossein (AS) hospital in Isfahan.

Protocol summary

Study aim

Comparison of fasciotomy of the testicular tunica albuginea outcomes in treating testicular torsion surgery in children

Design

This study is a non-blinded clinical trial with a parallel design and a control group. The research population will include all children with testicular torsion referred to Imam Hossein Hospital in Isfahan. A total of 64 eligible people will be selected conveniently. A simple random method is used for randomization and the participants are assigned to two intervention and control groups.

Settings and conduct

This study, which will be conducted in Imam Hossein Hospital in Isfahan city, is non-blinded. The right testicle is rotated counterclockwise and the left testicle is rotated clockwise and will be placed in warm wet gauze.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children with abdominal pain and testicular pain and testicular swelling and placement in a transverse position in the scrotum; diagnosis of testicular torsion according to ultrasound; Informed consent; Age less than 14 years Exclusion criteria: A testicle that has necrotic areas or is completely necrotic and there is no ability to hold the testicle; History of orchiopexy or inguinal hernia surgery

Intervention groups

The intervention group is the patients for whom fasciotomy, detorsion, and orchiopexy will be performed. Patients should undergo surgery within 6 hours. The control group is the patients for whom detorsion and orchiopexy will be performed without fasciotomy.

Main outcome variables

vascular spasms and flu; hematoma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N198**

Registration date: **2023-03-24, 1402/01/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-24, 1402/01/04**

Update count: **0**

Registration date

2023-03-24, 1402/01/04

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Name of ethics committee
Comparison of fasciotomy of the testicular tunica albuginea outcomes in treating testicular torsion surgery in children referred to Imam Hossein (AS) hospital in Isfahan.	Ethical Committee of medical School, Isfahan University of Medical Sciences
Public title	Street address
Comparison of fasciotomy of the testicular tunica albuginea outcomes in treating testicular torsion surgery in children	Vice Chancellor for Research Affairs, University Blvd., Arghwanieh, J Sharghi Street
Purpose	City
Treatment	Isfahan
Inclusion/Exclusion criteria	Province
Inclusion criteria:	Isfahan
Children with abdominal pain and testicular pain and testicular swelling and placement in a transverse position in the scrotum Diagnosis of testicular torsion according to ultrasound Informed consent Age less than 14 years	Postal code
Exclusion criteria:	8174673461
A testicle that has necrotic areas or is completely necrotic and cannot hold the testicle History of orchiopexy or inguinal hernia surgery	Approval date
Age	2022-05-23, 1401/03/02
From 14 years old	Ethics committee reference number
Gender	IR.MUI.MED.REC.1401.083
Male	
Phase	Health conditions studied
N/A	<u>1</u>
Groups that have been masked	Description of health condition studied
No information	Testicular rotation
Sample size	ICD-10 code
Target sample size: 64	ICD-10 code description
Randomization (investigator's opinion)	
Randomized	Primary outcomes
Randomization description	<u>1</u>
Randomization will be done in a simple random method, after identifying eligible patients, they will be randomly assigned a three-digit dedicated code. The last digit on the right determines the patient group. If this number is 0, 1, 2, 3, 4, it will be assigned in the first intervention group, and if this number is 5, 6, 7, 8, 9, it will be assigned in the second intervention group	Description
Blinding (investigator's opinion)	vascular spasms and flu
Not blinded	Timepoint
Blinding description	Before surgery, one hour and 24 hours after surgery
Placebo	Method of measurement
Not used	Sonography
Assignment	
Parallel	<u>2</u>
Other design features	Description
	Hematoma
Secondary Ids	Timepoint
empty	After surgery
Ethics committees	Method of measurement
<u>1</u>	Sonography
Ethics committee	Secondary outcomes
	empty
	Intervention groups
	<u>1</u>
	Description
	The intervention group is the patients for whom fasciotomy, detorsion, and orchiopexy will be performed. Patients should undergo surgery within 6 hours. First, the patient is put under general anesthesia, and after making a skin incision on the scrotum and opening the subcutaneous tissue and tunica vaginalis, the testicle is taken out first, detour is performed, and blood supply is

established. For torsion of the left testicle, first the testicle is rotated clockwise, and for the right testicle, we do the opposite, i.e. it is rotated counterclockwise. For fasciotomy, a cut is first made on the tunica albuginea, and a flap of the tunica vaginalis is placed on the incision site and fixed with PDS=4_0 thread (ethicon company).

Category

Treatment - Surgery

2**Description**

The control group is the patients for whom detorsion and orchiopexy will be performed without fasciotomy.

Category

Treatment - Surgery

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

Imam Hossein Hospital

Full name of responsible person

Dr. Mehrdad Hossinpour

Street address

Ostandari St., Imam Hossein Hospital

City

Isfahan

Province

Isfahan

Postal code

8174673581

Phone

+98 31 3386 6266

Email

Hossinpour@yahoo.com

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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Majid Meshkini

Street address

Vice Chancellor for Research and Technology, Building
No. 4, Isfahan University of Medical Sciences, Hezar
Jerib St.

City

Isfahan

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Postal code

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Phone

+98 31 3792 3071

Email

meshkini@miums.ac.ir

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mehrdad Hossinpour

Position

Member of the faculty of Isfahan University of Medical
Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric and neonatal surgery

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Isfahan University of Medical Sciences, Hezar Jarib St..

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

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available