

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of silicone gel application for reduction of scars after repair of hypospadias

Protocol summary

Summary

Hypospadias is one of most common genitalia abnormality in childhood. The goal of hypospadias repair is reconstruction of the penis directly with a meatus in the natural area and appropriate urine flow with normal shape and creating self confidence in a child. Fistula, stenosis, inaccessibility to a favorable condition due to the beauty and failure of treatment that requires re-operation is a major complication of surgical repair. One of the goals of achieving a beautiful appearance after surgery is to find a method to reduce the scar after the hypospadias repair. One of the most effective nonsurgical methods of scar treatment, based on scientific evidence, is using of silicone gel. Therefore, we decided to conduct a double-blind randomized trial, which patients and researcher measure the outcome of the study are unaware of the type of intervention, that investigate the effect of silicone gel on scar reduction after hypospadias repair.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080735551N1**
Registration date: **2017-08-21, 1396/05/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-21, 1396/05/30

Registrant information

Name

Iman Shamohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3232 6645

Email address

shamohammadi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz university of medical sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of silicone gel application for reduction of scars after repair of hypospadias

Public title

Efficacy of silicone gel application for reduction of scars after surgical wound healing

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: Patients undergoing hypospadias repair and referring to the clinic of Namazi Hospital after the surgery after obtaining informed consent. Exclusion: Patients who have an open wound or open wound infection or history of any allergy or skin disease, or the inability to follow the patient and complete the course of treatment.

Age

From **6 months** old to **7 years** old

Gender

Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization method The study design uses a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Research in Shiraz Medical School

Street address

Shiraz, Zand Avenue, opposite Palestine Street, Central Building of Shiraz University of Medical Sciences

City

Shiraz

Postal code

7134814336

Approval date

2017-07-23, 1396/05/01

Ethics committee reference number

IR.SUMS.MED.REC.1396.53

Health conditions studied

1

Description of health condition studied

Keloid scar

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

Height of scar

Timepoint

Before intervention and six months after the end of intervention

Method of measurement

With a ruler and scoring based on the Vancouver scar scale

2

Description

Vascularity of scar

Timepoint

Before intervention and six months after the end of intervention

Method of measurement

Observation and evaluation of post-white fill velocity due to pressure and scoring based on the Vancouver scar scale

3

Description

Pliability of scar

Timepoint

Before intervention and six months after the end of intervention

Method of measurement

Touch and scoring based on the Vancouver scar scale

4

Description

Pigmentation of scar

Timepoint

Before intervention and six months after the end of intervention

Method of measurement

view and scoring based on the Vancouver scar scale

Secondary outcomes

1

Description

Skin atrophy

Timepoint

Six months after the end of intervention

Method of measurement

Has or has not

Intervention groups

1

Description

Intervention group: Administration of silicone gel ointment on a lesion twice a day for two months

Category

Treatment - Drugs

2

Description

Control group: Administration of Vaseline ointment on a lesion twice a day for two months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Namazi Hospital

Full name of responsible person

Dr. Iman Shamohammadi

Street address

Shiraz, Zand Square, Namazi Hospital, Department of Urology

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Assistance of Research of Shiraz University of Medical Sciences

Full name of responsible person

Dr.Seyed Bassir Hashemi

Street address

Shiraz-Zand Avenue- Central Building of Shiraz University of Medical Sciences - 7th floor, Office of Assistance of Research

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Assistance of Research of Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz university of medical sciences

Full name of responsible person

Dr. Iman Shamohammadi

Position

Resident of Urology

Other areas of specialty/work

Street address

Shiraz-Namazi Hospital-Department of Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz university of medical sciences

Full name of responsible person

Dr. Mehdi Shirazi

Position

Surgeon and specialist of urology

Other areas of specialty/work

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Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident of urology

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty