

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the clinical results of salt therapy with surgery in treatment of umbilical granuloma in infants

Protocol summary

Summary

The aim of present study is to compare the clinical results of salt therapy with surgery in treatment of umbilical granuloma in infants. In a single center randomized clinical trial study, 50 patients with umbilical granuloma who referred to Children Hospital educational-medical center of Tabriz University of Medical Sciences will select randomly and with using randomly per muted blocks will allocate in two groups. Inclusion criteria are, infant age between 3 weeks to 4 month, diagnosis of umbilical granuloma, and parental informed consent for study. Exclusion criteria are infants older than 4 months, and other diagnosis except of umbilical granuloma. Patients were randomly will allocate in one of group. In first group umbilical granuloma will treat with salt therapy (n=25) and in second group umbilical granuloma will treat by surgery using electro-cauterization method (n=25). After treatment patients will followed up for 3 months. Patients will evaluate in term of successful treatment of umbilical granuloma as primary outcome variable and also will evaluate for rate of recurrence, and side effects of each both two treatments as secondary outcome variables.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042620663N3**

Registration date: **2016-05-14, 1395/02/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-14, 1395/02/25

Registrant information

Name

Davoud Badebarin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3526 2257

Email address

badebarind@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences.

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the clinical results of salt therapy with surgery in treatment of umbilical granuloma in infants

Public title

Comparison of the clinical results of salt therapy with surgery in treatment of umbilical granuloma in infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infant age between 3 weeks to 4 month; diagnosis of umbilical granuloma; parental informed consent for study. Exclusion criteria: infants older than 4 months; other diagnosis except of umbilical granuloma.

Age

From **1 month** old to **4 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University Of Medical Sciences

Street address

Tabriz University Of Medical Sciences, Daneshgah Street, Tabriz.

City

Tabriz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

TBZMED.REC.1394.564

Health conditions studied

1

Description of health condition studied

Umbilical Granuloma

ICD-10 code

L92.8

ICD-10 code description

Other granulomatous disorders of skin and subcutaneous tissue

Primary outcomes

1

Description

Successful treatment of umbilical granuloma

Timepoint

Five days after treatment.

Method of measurement

Clinical examination

Secondary outcomes

1

Description

Rate of recurrence

Timepoint

Three month after surgery.

Method of measurement

Clinical examination

2

Description

Side effects of treatment

Timepoint

Three months after surgery.

Method of measurement

Clinical examination

Intervention groups

1

Description

In intervention group: after washing umbilical area of infant by lukewarm water and drying it, we put some sterilized without iodine salt on granuloma to the extent that it covered all of granuloma surface, and after half an hour, will be washed with lukewarm water and will dried. This will be repeated every 12 hours for five days.

Category

Treatment - Other

2

Description

In control group: after general anesthesia, umbilical granuloma will be resect, using electric cautery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Hospital

Full name of responsible person

Dr. Davoud Badebarin

Street address

Department Of Surgery, Tabriz University of Medical Sciences.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University Of Medical Sciences.

Full name of responsible person

Dr Hasan Soleimanpour

Street address

Deputy of Research and Technology, Central Building of Number Two, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

City

Tabriz

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

Yes

Title of funding source

Vice chancellor for research, Tabriz 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**

Tabriz University Of Medical Sciences.

Full name of responsible person

Dr Mohammad Mehdi Shakeri

Position

Resident of Surgery Medicine

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Person responsible for scientific

inquiries

Contact**Name of organization / entity**

Department Of Surgery, Tabriz University of Medical Sciences.

Full name of responsible person

Dr. Davoud Badebarin

Position

Pediatric Surgery Sub-specialist.

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Dr Mohammad Mehdi Shakeri

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Resident of Surgery Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty