

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Study of the phenytoin spray using effects in prevention of fistula after cleft palate surgery in children

Protocol summary

Study aim

To evaluate the effects of phenytoin spray on the fistula formation prevention

Design

After primary repair surgery and taking informed consent, 160 patients with cleft palate consist of 80 patient in phenytoin group and 80 patient in control group conducted parallel double-blinded in the trial.

Settings and conduct

The trial performed in Tabriz Children Hospital in by managing study and control groups. Phenytoin spray 2% administered eight weeks. Physical examination performed every two weeks and at the end, by using the SPSS the data analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Using phenytoin spray 2%, correct use the spray, regular use the spray Exclusion criteria: Revision surgery, soft palate cleft atypical Cleft, complication of phenytoin spray, past medical history of seizure and systemic diseases, using anti convulsant, anti hypertension, and immune suppressant drugs

Intervention groups

In the group treated with phenytoin, phenytoin spray 2% every four hours following washing and drying the mouth following feeding for eight months described and the control group not received any medication for fistula prevention

Main outcome variables

Palate fistula formation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180802040678N3**

Registration date: **2019-09-16, 1398/06/25**

Registration timing: **retrospective**

Last update: **2019-09-16, 1398/06/25**

Update count: **0**

Registration date

2019-09-16, 1398/06/25

Registrant information

Name

Masoud Nouri-Vaskeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3325 9778

Email address

mnvaskeh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2010-03-01, 1388/12/10

Expected recruitment end date

2015-02-01, 1393/11/12

Actual recruitment start date

2010-03-01, 1388/12/10

Actual recruitment end date

2015-02-01, 1393/11/12

Trial completion date

2015-02-01, 1393/11/12

Scientific title

Study of the phenytoin spray using effects in prevention of fistula after cleft palate surgery in children

Public title

Study of the phenytoin spray using effects in prevention of fistula after cleft palate surgery in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Having a combined hard and soft palate Aged between 2 months to 2 years old

Exclusion criteria:
Revision surgery of cleft palate Soft palate cleft only Atypical Cleft Past medical history of seizure and systemic diseases Using anti convulsant, anti hypertension, and immune suppressant drugs

Age
To **15 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Children who have eligibility criteria were stratified (1:1) into the phenytoin and control groups according to their cleft palate width. Allocation to the phenytoin and control groups was performed according to randomized number table.

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

516615731

Approval date

2018-07-28, 1397/05/06

Ethics committee reference number

IR.TBZMED.REC.1397.961

Health conditions studied

1

Description of health condition studied

Cleft Palate

ICD-10 code

Q35.5

ICD-10 code description

Cleft hard palate with cleft soft palate

Primary outcomes

1

Description

Fistula Formation

Timepoint

After eight weeks

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Administration of phenytoin spray 2% severly four hours for eight weeks

Category

Prevention

2

Description

Control group: Receiving nothing

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children's Hospital of University of Medical Sciences

Full name of responsible person

Mohamad Amin Fakhriniya

Street address

Sheshgelan street

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3526 2251

Fax

+98 41 3526 2251

Email

kodakanhospital@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Research Vice-Chancellor of Tabriz University of Medical Sciences

Street address

Golgasht Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

516615731

Phone

+98 41 3335 7314

Email

research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Masoud Nouri-Vaskeh

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Golgasht Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

516615731

Phone

+98 41 3325 9778

Email

mnvaske@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Shahin Abdollahi Fakhim

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Sheshgelan Street

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3526 2251

Email

abdollahifakhim85@hotmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohamad Amin Fakhrianiya

Position

Researcher

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Sheshgelan Street

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3526 2251

Email

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

Information about the study is available upon approval

by the University's Ethics Committee.

When the data will become available and for how long

Starting access 6 months after publication of data

To whom data/document is available

Everybody

Under which criteria data/document could be used

After communication with the corresponding author of the project, the researchers in this field can access some statistical analysis file information.

From where data/document is obtainable

Principal Investigator Dr. Shahin Abdollahi Fakhim,
Department of Ear, Nose, and Throat, Tabriz University of
Medical Sciences, email:
abdollahifakhim85@hotmail.com

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

After email to the corresponding author of the project, they will be able to access to the data.

Comments