

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation and comparison of surgical outcomes of frenectomy in infants with ankyloglossia using electrocautery or surgical in Tabriz pediatric hospital

Protocol summary

Study aim

Determination of complications of phryngotomy (bleeding, infection, movement limitation and tongue dysfunction) in neonates with ankylosing spondylitis using electrocautery and incision surgery

Design

Clinical trial with control group, with parallel, non-blind, simple randomized groups, on 20 patients. Excel software rand function was used for randomization.

Settings and conduct

Sampling is done after receiving the code of ethics from the university ethics committee. Patients will be randomly selected from patients referred to the ENT surgery clinic of Tabriz Children's Hospital. Diagnosis is by clinical examination and parental history. Patients will be selected based on the criteria of admission (parental consent and definitive diagnosis with history and clinical examination) and exclusion (unwillingness to continue treatment at any stage) and will be randomly divided into one of two groups A and B.

Participants/Inclusion and exclusion criteria

Age 6 months to 2 years; No previous procedure for ankyloglossia; Acceptance of research terms and procedures by parents; Lack of effective oral and tongue disease in the study results; Diagnosis of Ankyloglossia

Intervention groups

Intervention group: Using electrocautery (instead of surgery) for tongue phrenctomy. This method is safer and faster and has fewer complications Control group: Patients in this group undergo traditional surgical phrenctomy.

Main outcome variables

Freedom of tongue movement in the mouth; Improves infant feeding

General information

Reason for update

Reducing the number of samples from 60 to 40. Due to the conditions and the spread of Covid-19

Acronym

فرنولوم زبان

IRCT registration information

IRCT registration number: **IRCT20150114020663N7**

Registration date: **2021-10-31, 1400/08/09**

Registration timing: **prospective**

Last update: **2022-12-25, 1401/10/04**

Update count: **1**

Registration date

2021-10-31, 1400/08/09

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

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation and comparison of surgical outcomes of frenectomy in infants with ankyloglossia using electrocautery or surgical in Tabriz pediatric hospital

Public title
Evaluation and comparison of surgical outcomes and complications of frenectomy in infants with ankyloglossia using electrocautery or surgical in Tabriz pediatric hospital

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 age 6 months to 2 years No previous procedure for ankyloglossia Acceptance of research terms and procedures by parents Lack of effective oral and tongue disease in the study results Diagnosis of Ankyloglossia
Exclusion criteria:
 Age above 2 years Previous surgery on the tongue Severe adhesion of the tongue to the floor of the mouth Another severe underlying disease

Age
From **6 months** old to **2 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to intervention and control groups. Patients are distributed in two groups (random sequence) using a table of random numbers. Patients are divided between the two groups by announcing the number of patients in the clinic. Odd numbers in one group and even numbers in the second group. Patients are selected in the clinic of Tabriz Children's Hospital

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 St., Azadi St

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-10-04, 1400/07/12

Ethics committee reference number

IR.TBZMED.REC1400.634

Health conditions studied

1

Description of health condition studied

Ankyloglossia

ICD-10 code

Q38.1

ICD-10 code description

Ankyloglossia

Primary outcomes

1

Description

Answer to surgical or electrocautery treatment of the tongue ferronolum

Timepoint

6 months

Method of measurement

Physical examination

Secondary outcomes

1

Description

Good baby nutrition

Timepoint

6month and 1 year

Method of measurement

Weighing

Intervention groups

1

Description

Intervention group: Electrocautery. In this group of patients, the patient's tongue follicle is removed using the cauterization device in the operating room of Tabriz Children's Hospital. The cutter degree is set to cut 8. The incision is performed by the surgeon in one session and after the end of the work, the patient is monitored for recovery from bleeding under the tongue and edema.

Category

Treatment - Surgery

2

Description

Control group: surgery. In this group, patients undergo tongue follicle resection by traditional surgical method after general anesthesia using anesthesia and restoration with 0.4 vicryl suture. It is controlled for bleeding under the tongue and edema.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Childeren Hospital

Full name of responsible person

Davoud Badebarin

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Daneshgah Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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.

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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

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

Davoud Badebarin

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric Surgeon

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Medical Faculty, Adjacent to the Emam Reza hospital, Golgasht Street

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Davoud Badebarin

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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

"No more 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