

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Assessment of unilateral palatal cleft size and surgical outcome in patients treated with and without feeding plate

#### Protocol summary

##### Study aim

Determination palatal cleft size a surgical outcome in patient with unilateral cleft treated with and with out Feeding plate

##### Design

One arm parallel group randomised trial with out blind out come assessment

##### Settings and conduct

Both case and control groups in Amir cola hospital gone under palatoplasty

##### Participants/Inclusion and exclusion criteria

9-12 month patient with non syndromic unilateral palatal cleft with out surgery

##### Intervention groups

case group will have feeding plate before surgery and control group have not feeding plate

##### Main outcome variables

effect of feeding plate on cleft size effect of feeding plate on surgical out come

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180411039261N1**  
Registration date: **2018-05-23, 1397/03/02**  
Registration timing: **registered\_while\_recruiting**

Last update: **2018-05-23, 1397/03/02**

Update count: **0**

##### Registration date

2018-05-23, 1397/03/02

##### Registrant information

##### Name

Mansoureh Mohamadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3229 7951

##### Email address

mansoureh.mohamadi@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-09, 1397/02/19

##### Expected recruitment end date

2018-07-10, 1397/04/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of unilateral palatal cleft size and surgical outcome in patients treated with and without feeding plate

##### Public title

Assessment effect of Feeding plate on Palatal cleft

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patient 9-12 month with n palatal cleft

##### Exclusion criteria:

Syndromic patient Previous palate surgery Bilateral palatal cleft

##### Age

From **9 months** old to **12 months** old

##### Gender

Both

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: 12

**Randomization (investigator's opinion)**

Not 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**

Ethics committee of Babol Univercity of Medical Science

**Street address**

Dentestry Univercity, Felestin Ave, Velayat Square, Babol Town

**City**

Babol

**Province**

Mazandaran

**Postal code**

47176-43633

**Approval date**

2018-03-18, 1396/12/27

**Ethics committee reference number**

MUBABOL.HRI.REC.1396.217

**Health conditions studied**1**Description of health condition studied**

palatal cleft

**ICD-10 code**

Q35.5

**ICD-10 code description**

Cleft hard palate with cleft soft palate

**Primary outcomes**1**Description**

surgical outcome

**Timepoint**

7days and 1month after surgery

**Method of measurement**

Objection

**Secondary outcomes**

empty

**Intervention groups**1**Description**

Intervention group:patient with unilateral cleft whome had Feeding plate before surgery at the first week of life.

**Category**

Treatment - Devices

2**Description**

Control group: patient with unilateral cleft whom had palatoplasty surgery at 9 month yaers old.

**Category**

Treatment - Devices

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

Babol dental Univercity

**Full name of responsible person**

Mansoure Mohamadi

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

Babol University of Medical Sciences

**Full name of responsible person**

reza ghadimi

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mansoureh.mohamadi@mubabol.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Babol 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**  
Babol University of Medical Sciences  
**Full name of responsible person**  
Mansoureh Mohamadi  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

main out come will share

**When the data will become available and for how long**

6 month after out comes publised

**To whom data/document is available**

Academic researcher

**Under which criteria data/document could be used**

only Documents sorce

**From where data/document is obtainable**

Babol Dental Univercity

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

1 month after Email recivement

**Comments**