Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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: pationt 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
Street address
Dental univercity, felestin Ave, Velayat Square
City
Babol
Province
Mazandaran
Postal code
47176-43633
Phone
+98 11 3229 1408
Email
mansoureh.mohamadi@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
reza ghadimi
Street address
Dentestre univercity, Felestin Ave, Velayate Square
City

Babol
Province
Mazandaran
Postal code
47176-43633
Phone
+98 11 3229 1408
Email
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
Street address
Department of oral and maxillofacial surgery,Dentistry university, Felestin sttreet, Velayat square, Babol Town
City
Babol
Province
Mazandaran
Postal code
47176-43633
Phone
+98 21 3229 7951
Fax
Email
mansoureh.mohamadi@mubabol.ac.ir

Person responsible for scientific 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
Street address
Department of oral and maxillofacial surgery,Dentistry university, Felestin sttreet, Velayat square, Babol Town
City
Babol
Province
Mazandaran
Postal code
47176-43633
Phone
+98 21 3229 7951
Fax
Email
mansoureh.mohamadi@mubabol.ac.ir

Person responsible for updating data

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
Street address
Department of oral and maxillofacial surgery,Dentistry university, Felestin sttreet, Velayat square, Babol Town
City
Babol
Province
Mazandaran
Postal code
47176-43633
Phone
+98 21 3229 7951
Fax
Email
mansoureh.mohamadi@mubabol.ac.ir

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