

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of effectiveness of non-pharmacological and herbal treatments in reducing complications of the primary teeth eruption in children 5 to 15 months

Protocol summary

Summary

In this clinical study, 450 children between 5 and 15 months old are selected through simple sampling method from health centers in deprived areas of Shiraz. The Inclusion criteria are normal birth weight (≤ 2500 g), fullterm and healthy neonates and children with at least one primary teeth not erupted. The exclusion criteria are children with infectious diseases, syndromic children and children with systemic diseases. Data are collected in four stages: 1. When there are no signs of teeth eruption (first examination session - Selection Session) 2. During the 4 days before the eruption (second session). 3. Eruption day (third session). 4. During the 4 days after the eruption (fourth session) Intervention groups: 1. Eruption Control: no specific treatment is done and behavioral therapy is used only. 2. Nonpharmacologic treatments: the group is trained with the distribution of pamphlets on primary teeth eruption and potential problems within it. Also to treat symptoms of tooth eruption, nonpharmacologic treatments are suggested, such as using cold-tooth rings, pacifiers freezer, small retailers, gauze or wet towel, massaging the baby's gums with a clean finger or a finger toothbrush for 1 -2 minutes. 3. Herbal treatments: the group is trained with the distribution of pamphlets on primary teeth eruption, Herbal treatments of eruption symptoms are taught to parents such as licorice root for chewing or massaging the gum with the chamomile or olive oil.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211127402N3**

Registration date: **2012-11-26, 1391/09/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-11-26, 1391/09/06

Registrant information

Name

Mahtab Memarpour

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1626 3192

Email address

memarpour@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of non-pharmacological and herbal treatments in reducing complications of the primary teeth eruption in children 5 to 15 months

Public title

Comparison of non pharmacological methods in reducing

complications of the primary teeth eruption

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Normal birth weight (≤ 2500 g); Fullterm and healthy neonates; with at least one primary teeth not erupted. Exclusion criteria: Children with infectious diseases; Syndromic children; Children with systemic diseases.

Age
From **1 year** old to **2 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **450**

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
Shiraz University of Medical Sciences

Street address
Pediatric Dentistry Department, Faculty of Dentistry,
Ghomabad, Ghasrodasht

City
Shiraz

Postal code

Approval date
2012-11-07, 1391/08/17

Ethics committee reference number
CT-91-6317

Health conditions studied

1

Description of health condition studied
Complications of the primary teeth eruption

ICD-10 code
K00.6

ICD-10 code description
Disturbances in tooth eruption

Primary outcomes

1

Description
Fever

Timepoint
Beginning of the research, Fourth day, Eighth day,
Eleventh day

Method of measurement
Thermometer, Questionnaires, Physical examination,
Observation

2

Description
Pain

Timepoint
Beginning of the research, Fourth day, Eighth day,
Eleventh day

Method of measurement
, Questionnaires, Physical examination, Observation

3

Description
Drooling

Timepoint
Beginning of the research, Fourth day, Eighth day,
Eleventh day

Method of measurement
Questionnaires, Physical examination, Observation

4

Description
Diarrhea

Timepoint
Beginning of the research, Fourth day, Eighth day,
Eleventh day

Method of measurement
Questionnaires

Secondary outcomes

empty

Intervention groups

1

Description
1. Eruption Control: no specific treatment is done and behavioral therapy is used only.

Category
Behavior

2

Description

2. Nonpharmacologic treatments: the group is trained with the distribution of pamphlets on primary teeth eruption and potential problems within it. Also to treat symptoms of tooth eruption, nonpharmacologic treatments are suggested, such as using cold-tooth rings, pacifiers freezer, small retailers, gauze or wet towel, massaging the baby's gums with a clean finger or a finger toothbrush for 1 -2 minutes

Category

Other

3

Description

3. Herbal treatments: the group is trained with the distribution of pamphlets on primary teeth eruption, Herbal treatments of eruption symptoms are taught to parents such as licorice root for chewing or massaging the gum with the chamomile or olive oil.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Saadi Health Center

Full name of responsible person

Maryam Ostovar

Street address

Neyestan Boulevard, Saadi Street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Ali Poust Foroushfard

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

Position

Associate Professor of Pediatric Dentistry / Faculty

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mahtab Memarpour

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Mahtab Memarpour

Position

Associate Professor of Pediatric Dentistry / Faculty

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Web page address**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