

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

The effect of chlorhexidine mouthwash on gingival health around stainless steel crowns on deciduous molars

Protocol summary

Study aim

evaluation of The effect of chlorhexidine mouthwash on gingival health around stainless steel veneers in deciduous molars

Design

Clinical trial with control group with parallel and double-blind groups, phase three on 58 patients

Settings and conduct

Ahvaz Jundishapur Dental School researcher and measurer were blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The child is over 4 years old and has the ability to spit mouthwash, has no history of antibiotics in the past 4 weeks, no signs of periodontal disease and interdental bone resorption on the radiograph of the patient, no use of orthodontic applique, history Has no systemic disease, no history of fluoride use in the last 2 weeks Exclusion criteria: non-cooperation of the child, use of antibiotics during treatment, performing other dental treatments in other medical centers by the patient

Intervention groups

The intervention group is given chlorhexidine after treatment (putpotomy and veneer of deciduous teeth) to evaluate the effect of this mouthwash on improving gingivitis.in control group after same treatment no mouthwash prescribe.

Main outcome variables

gingival index,Oral hygiene index (OHIS), probing depth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210417050994N1**

Registration date: **2021-05-24, 1400/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-24, 1400/03/03**

Update count: **0**

Registration date

2021-05-24, 1400/03/03

Registrant information

Name

shiva motaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3865 4216

Email address

shivamotaghi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-10, 1400/02/20

Expected recruitment end date

2021-06-10, 1400/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of chlorhexidine mouthwash on gingival health around stainless steel crowns on deciduous molars

Public title

evaluation of the effect of chlorhexidine mouthwash on gingival health around stainless steel crowns on deciduous molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age more than 4 year-old ability to spit had not uses antibiotics in the last 4 weeks doesn't have periodontal diseases and inter proximal bone lost not using orthodontic appliances doesn't have systemic diseases had not uses fluoride in the last 2weeks

Exclusion criteria:

lack of cooperation using antibiotics during the treatment being under treatment in other dentistry departments

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The researcher and outcome assessor does not know whether the patient has used mouthwash or not

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of ahvaz jundishapur university of medical sciences

Street address

golestan blvd. jundishapur university

City

ahvaz

Province

Khuzestan

Postal code

15794 - 61357

Approval date

2021-04-18, 1400/01/29

Ethics committee reference number

IR.AJUMS.REC.1400.036

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

gingivitis

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

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

Gingival Index (Gingival Index): 0- Healthy gums 1- Low inflammation: low discoloration, low edema, no bleeding 2- Moderate inflammation: gingival redness, edema and shine, bleeding gums during probing 3- Severe inflammation: Distinct redness and edema, sores, tendency for spontaneous bleeding of the gums.

Timepoint

two weeks after using chlorhexidine mouthwash

Method of measurement

observational

2**Description**

OHIS: - 1- Soft debris that covers less than one third of the tooth surface 2- Soft debris that covers between one third and two thirds of the tooth surface 3- Soft debris that covers more than two thirds of the tooth surface

Timepoint

two weeks after using chlorhexidine mouthwash

Method of measurement

observational

3**Description**

probing depth

Timepoint

two weeks after using chlorhexidine mouthwash

Method of measurement

by using periodontal probe

Secondary outcomes

empty

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

Intervention group: The group that used chlorhexidine mouthwash for two weeks after pulpotomy and stainless steel coating treatment.the 012 percent vi- one chlorhexidine is pour on the cotton and apply on the teeth gingiva.this should be done once in a day

Category

Treatment - Other

2**Description**

Control group: the group that does not use chlorhexidine mouthwash

Category

Other

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

ahvaz jundishapur dentistry school

Full name of responsible person

shiva motaghi

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

Ahvaz University of Medical Sciences

Full name of responsible person

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Grant name

Ahvaz university of medical sciences

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

shiva motaghi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

resident

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

not clear

When the data will become available and for how long

not clear

To whom data/document is available

when our article is published

Under which criteria data/document could be used

not clear

From where data/document is obtainable

not clear

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

not clear

Comments