

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of preoperative chlorhexidine mouthwash on pain after lower posterior teeth removal : A Randomized, Double blind Clinical Trial

Protocol summary

Study aim

The purpose of this study is to investigate the influence of 0.2% (w/v) chlorhexidine gluconate mouthwash on the severity of post-extraction pain.

Design

A parallel, double blind, single center controlled trial sample size is 170

Settings and conduct

0.5 to 1 h before performing extractions, subjects will be given a dark bottle containing 15 ml of either chlorhexidine 0.2% or placebo. Patients will be asked to rinse the assigned solutions around their mouth for two minutes before spitting out. Subjects undergo the operation under local anesthesia with one 1.8-ml capsule of 2% lidocaine and 1:80 000 Epinephrine. Postoperative pain will be assessed by considering the following parameters: (1) pain will be evaluated using a visual analog scale (VAS); (2) the number of analgesic tablets ingested. Patients' postoperative pain and analgesic intake will be recorded by 4 telephone interviews 6, 12, 24 and 48 h after tooth extraction.

Participants/Inclusion and exclusion criteria

To be eligible for the study the patients have to be between 18 and 80 years old. patients be healthy and not on any regular medication. No patient have any of pain inducing conditions such as an aching tooth at the time of the surgery.

Intervention groups

chlorhexidine group (study group) placebo (control group)

Main outcome variables

Pain after tooth extraction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121223011856N2**

Registration date: **2019-04-25, 1398/02/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-25, 1398/02/05**

Update count: **0**

Registration date

2019-04-25, 1398/02/05

Registrant information

Name

daryoosh hasheminia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 325 7106

Email address

haghighat@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of preoperative chlorhexidine mouthwash on pain after lower posterior teeth removal : A Randomized, Double blind Clinical Trial

Public title

Effect of Chlorhexidine on postextraction pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

patients will be between 18 and 80 years old. patients be healthy and not on any regular medication. patients will not have any of pain inducing conditions such as an aching tooth at the time of the surgery.

Exclusion criteria:

patients will be excluded if they ingested any medications including oral contraceptives, analgesics and antibiotics as of 5 days prior to the operation. smokers will be excluded

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated to a treatment group based on the flip of a coin.

Blinding (investigator's opinion)

Double blinded

Blinding description

0.5 to 1 h before performing extractions, subjects will be given a dark bottle containing 15 ml of either chlorhexidine 0.2% or placebo but they have no idea of the type of the solution. we will ask the clinician to perform extractions in equal situation for all patients while he has no information about the two groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical science

Street address

Hezarjarib st

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2018-12-29, 1397/10/08

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.482

Health conditions studied

1

Description of health condition studied

postoperative pain after tooth extraction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

patients pain

Timepoint

6,12,24 and 48 hours after extractio

Method of measurement

patients pain will be assessed using a VAS (Visual Analog Scale) and the number of analgesic used

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 0.5 to 1 hours before performing extractions patient in intervention group will be given a dark bottle containing 15 ml of 0.2% chlorhexidine gluconate mouthwash (BEHSA). they will rinse the solution around their mouth for two minutes. the extractions will be done by an expert clinician. After performing extractions, patients will receive 10 pills of Acetaminophen 325 (EXIR) to be taken in case of excessive pain. patient analgesic intake and postoperative pain will be recorded by 4 telephone interviews 6, 12, 24 and 48 postoperative hours. Subjects will be asked to make VAS evaluation of their pain. Likewise subjects will be asked if they have used any prescribed analgesics and if so, the dosage will be asked.

Category

Prevention

2

Description

Control group: 0.5 to 1 hours before performing

extractions patient in control group will be given a dark bottle containing 15 ml of placebo mouthwash (one liter of placebo contains 1 liter of sterile normal saline (Samen company) plus one drop of natural edible colours made by colour splash company) . they will rinse the solution around their mouth for two minutes. the extractions will be done by an expert clinician. After performing extractions, patients will receive 10 pills of Acetaminophen 325 (EXIR) to be taken in case of excessive pain. patient analgesic intake and postoperative pain will be recorded by 4 telephone interviews 6, 12, 24 and 48 postoperative hours. Subjects will be asked to make VAS evaluation of their pain. Likewise subjects will be asked if they have used any prescribed analgesics and if so, the dosage will be asked.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University of Medical science

Full name of responsible person

Shaqayeq Ramezanzade

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Abbas Haghighat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

Abbas Haghighat

Position

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Latest degree

Specialist

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Person responsible for updating data

Contact

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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

"There is no further 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