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 controlld 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)

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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 postextrction 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

Isfehan

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
Ŝhaqayeq Ramezanzade

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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 Haghaighat

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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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