

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of Benzydamine HCl 0.15% mouthwash and Ibuprofen effect on pain relief after crown lengthening, a clinical trial

Protocol summary

Summary

Objectives: To determine the effect of Benzydamine hydrochloride mouthwash and ibuprofen to reduce pain after crown lengthening surgery and determine the average pain scores between the two groups. Design: Ethics Committee approval (number 63 942) and written consent from patients will be taken. Surgery by a two-year surgical resident will be done. surgical techniques will be the same for all patients. Operative pain in the first 24 hours after surgery were recorded. Setting and conduct: patients divided into two equal groups. The first group is requested to rinse Benzydamine hydrochloride mouthwash 0.15 % every 3 hours for 30 seconds and the second group will be asked to take a ibuprofen 400 mg pill every 6 hours. Major Inclusion and Exclusion criteria: Inclusion criteria include Contact periodontal status; require surgery on the posterior teeth; not taking any painkillers or anti-inflammatory during the last 6 months; lack of systemic problems; no contraindications for ibuprofen or benzydamine and exclusion criteria include lack of desire to participate in the plan; effective pain medication during the past 6 months, the risk of systemic problems affecting the periodontal tissues, ibuprofen or Benzydamine is contraindicated. Intervention: Intervention group: rinse with benzydamine hydrochloride mouthwash 0.15% (the pharmaceutical company "Exir" Boroujerd) at a rate of once every 3 hours 15 ml for 30 seconds in mouth. Control group: consume ibuprofen 400 mg tablets every 6 hours (the pharmaceutical company "Hakim"). The main outcome variables: age, sex, VAS

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012312847N2**

Registration date: **2016-03-02, 1394/12/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-02, 1394/12/12

Registrant information

Name

Arezoo Khabazian

Name of organization / entity

Shahid Sadoghi University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 35 1822 8852

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Recruitment status

Recruitment complete

Funding source

Shahid Sadooghi University Of Medical Sciences

Expected recruitment start date

2016-02-04, 1394/11/15

Expected recruitment end date

2016-06-09, 1395/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Benzydamine HCl 0.15% mouthwash and Ibuprofen effect on pain relief after crown lengthening, a clinical trial

Public title

Comparison of Benzydamine HCl 0.15% mouthwash and Ibuprofen effect on pain relief after crown lengthening, a clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Periodontal health establishment: require crown lengthening surgery in the posterior teeth: avoiding the use of any painkiller or anti-inflammatory or Counter during the last 6 months: lack of systemic problems: lack of contraindications of ibuprofen or Benzylamine hydrochloride mouthwash. Benzylamine hydrochloride contraindications include hypersensitivity to the drug or formulation components: children under 12 years of age: past medical history and feed intake. Warning of eye contact with the drug. The classification used in pregnancy: is in category C. It should not be administered to a patient more than 7 days: and in case of allergies: medication should be discontinued. Information on medication safety in nursing mothers. Contraindications Ibuprofen include third trimester of pregnancy (the drugs X): such as anaphylaxis or Angioedema history of severe allergic reaction caused by aspirin or other non steroidal anti-inflammatory drugs or nose polyp with spasticity due to an inflammatory disease or ulcerative the upper or lower gastrointestinal tract : hemophilia and other blood disorders: including disorders of hemostasis: or platelets: kidney disorders : stomatitis and elderly patients and patients the risk of gastrointestinal bleeding and ulcers in them is high. Concomitant use of ibuprofen with inhibitors of angiotensin converting enzyme (ACE): one of the quinolone antibacterial agents: hypoglycemic sulfonyleurea drugs: cyclosporine: lithium and methotrexate may: anticoagulants or thrombolytic: triamterene: valproic acid: aspirin and performance they interference is increasing or decreasing. Exclusion criteria: Unwillingness to participate in the plan: effective pain medications (analgesics or anti-inflammatory drug or drug) during the last 6 months: the risk of systemic problems affecting the periodontal tissues (diabetes: hypertension and heart disease: vascular): ibuprofen is contraindicated or mouthwash Benzylamine hydrochloride.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 36

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Table of random numbers

Secondary Ids

1

Registry name

000

Secondary trial Id

000

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadooghi University Of Medical Sciences

Street address

Dahe Fajr Blv, Yazd

City

Yazd

Postal code

Approval date

2015-06-21, 1394/03/31

Ethics committee reference number

IR.SSU.REC.1394.30

Health conditions studied

1

Description of health condition studied

crown lengthening surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

24 hours after intervention

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

stinging & numbness

Timepoint

24 hours after intervention

Method of measurement

asking from patient

Intervention groups

1

Description

Intervention group: rinse with benzydamine hydrochloride mouthwash 0.15% (the pharmaceutical company "Exir" Boroujerd) at a rate of once every 3 hours 15 ml for 30 seconds in mouth.

Category

Treatment - Drugs

2

Description

Control group: consume ibuprofen 400 mg tablets every 6 hours (the pharmaceutical company "Hakim").

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadooghi University Of Medical Sciences

Full name of responsible person

Arezoo Khabazian

Street address

Dahe Fajr Blv, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Sadooghi University Of Medical Sciences

Full name of responsible person

Dr Amir Hooshang Mehrparvar

Street address

Shahid Bahonar Square, Yazd

City

Yazd

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Shahid Sadooghi 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

Shahid Sadooghi University Of Medical Sciences

Full name of responsible person

Arezoo Khabazian

Position

professor assistant of periodontology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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