

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the effect of Protact mouth rinse on topical side effects of wisdom teeth extraction and comparison with control group

Protocol summary

Study aim

Evaluation of the effect of Protact mouthwash on local complications caused by wisdom tooth surgery

Design

A clinical trial with a control group, single-blind, randomized, crossover, on 33 patients, the kitset.ir site was used for randomization.

Settings and conduct

This study will be performed by one-blind clinical trial. The population of this study includes patients who are candidates for bilateral mandibular wisdom tooth surgery who refer to the dental clinic of Babol University of Medical Sciences. Due to the blindness of the research method, the surgeon will not know how to code mouthwashes.

Participants/Inclusion and exclusion criteria

Inclusion criteria include the following: 1- Existence of two occult or semi-occult wisdom teeth in the mandible that have almost the same appearance on both sides and both sides are operated by one surgeon. 2 - Age minimum 18 years and maximum 30 years 3- Healthy oral mucosa Exclusion criteria are: 1- Being a smoker 2- Any systemic conditions; Such as liver and kidney diseases, fever, neutropenia, diabetes, autoimmunity

Intervention groups

Patients receiving Protact mouthwash. Patients receiving normal saline mouthwash.

Main outcome variables

Wound healing rate and pain rate

General information

Reason for update

Reducing the sample size to 20 patients

Acronym

IRCT registration information

IRCT registration number: **IRCT20220220054070N1**

Registration date: **2022-07-22, 1401/04/31**

Registration timing: **prospective**

Last update: **2022-11-12, 1401/08/21**

Update count: **1**

Registration date

2022-07-22, 1401/04/31

Registrant information

Name

mohammad mahdi mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Protact mouth rinse on topical side effects of wisdom teeth extraction and comparison with control group

Public title

Evaluation of the effect of Protact on oral ulcerations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Existence of two occult or semi-occult wisdom teeth in the mandible that have almost the same view on both sides and both sides are operated by a surgeon Age minimum 18 years and maximum 30 years Healthy oral mucosa without mucosal or infectious lesions

Exclusion criteria:

Being a smoker Any systemic conditions; Such as liver and kidney diseases, fever, neutropenia, diabetes, autoimmunity

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each patient undergoes mandibular wisdom tooth extraction twice (once for the left and once for the right) and receives one of the proactive or normal saline mouthwashes for each operation.

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method was performed through the site that patients are divided into two groups that each group of people in the first surgery receive a type of mouthwash and in the second surgery, receive a second mouthwash.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the blindness of the research method, the surgeon will be unaware of how to code mouthwashes.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Ganjafruz st.

City

Babol

Province

Mazandaran

Postal code

4818898435

Approval date

2022-04-25, 1401/02/05

Ethics committee reference number

IR.MUBABOL.REC.1401.025

Health conditions studied

1

Description of health condition studied

Localized erythema of the mouth and pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Status of local mucosal erythema at the surgical site including no erythema, mild to moderate erythema and severe erythema

Timepoint

results3 and 7 days after surgery

Method of measurement

Lesions are visually examined and evaluated.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They receive Protact mouthwash containing thyme extract. Each patient is told to rinse their mouth with 5 ml of mouthwash for 1 minute twice a day, morning and night, one hour after brushing, and until An hour later, do not rinse your mouth with water and avoid eating and drinking. Start this night after surgery and continue for a week.

Category

Treatment - Drugs

2

Description

Control group: Receive mouthwash containing normal saline. Each patient is told to rinse his mouth with 5 ml of mouthwash for 1 minute for 1 minute in the morning and evening, one hour after brushing, and Do not rinse your mouth with water for an hour after that and avoid eating and drinking. Start on the night of surgery and continue for a week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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Ganj Afrooz St., School of Dentistry, Babol University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

student research committee babol university of medical sciences

Grant code / Reference number

724134320

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

Yes

Title of funding source

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Mohammadi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Fax**Email**

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

Undecided - It is not yet known if there will be 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