

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of the Effect of an Innovative Combination Solution Containing: Amoxicillin, Betamethasone and Ibuprofen on Controlling pain, Swelling and Infection Caused by Wisdom Tooth Surgery

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Evaluation of the Effect of an Innovative Combination Solution Containing: Amoxicillin, Betamethasone and Ibuprofen on Controlling pain, Swelling and Infection Caused by Wisdom Tooth Surgery

Last update: **2021-10-26, 1400/08/04**

Update count: **0**

Registration date

2021-10-26, 1400/08/04

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 40 patients.

Registrant information

Name

pouya mansourian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

A total of 40 patients who comply with the inclusion criteria are admitted with the patient's consent. First, it is randomly selected which side of each patient's face should be operated on first. Then, by simple random method, it is determined in which side, as a control group, the foam gel alone and on the opposite side, the foam gel saturated with a compound containing amoxicillin, betamethasone and ibuprofen, which is combined and is in the form of a gel, is kept silent. The data should be sutured immediately to keep the jellum still in place. Both the patient and the researcher are blind to the study.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Has erupted wisdom teeth
Absence of systemic disease
Proper oral hygiene

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-07-23, 1401/05/01

Intervention groups

Placing amoxicillin, betamethasone and ibuprofen-saturated gelfum in the wisdom tooth

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

the pain
Inflammation
Infection
impurity

Trial completion date

empty

General information

Scientific title

Evaluation of the Effect of an Innovative Combination Solution Containing: Amoxicillin, Betamethasone and Ibuprofen on Controlling pain, Swelling and Infection Caused by Wisdom Tooth Surgery

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210818052227N1**

Registration date: **2021-10-26, 1400/08/04**

Public title

Evaluation of the Effect of an Innovative Combination Solution Containing: Amoxicillin, Betamethasone and Ibuprofen on Controlling pain, Swelling and Infection Caused by Wisdom Tooth Surgery	
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Has erupted wisdom teeth Absence of systemic disease Proper oral hygiene
Exclusion criteria:	systemic disease Improper oral hygiene
Age	From 18 years old
Gender	Both
Phase	N/A
Groups that have been masked	- Participant - Investigator
Sample size	Target sample size: 40
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, both interventions are performed in all patients. All 40 patients are given numbers from 1 to 40. In the first step, using a simple random method using a random number table, we identify 20 patients whose first surgery is on the left and another 20 patients whose first surgery is on the right. In the second stage, for 20 patients whose first surgery is on the left, using a simple random method, using a table of random numbers, we determine which 10 patients have the first surgery of a gel saturated with a combination of amoxicillin, betamethasone and ibuprofen. Which other 10 people use foam gel alone (control group). We repeat this for 20 people whose first surgery is on the right side.
Blinding (investigator's opinion)	Double blinded
Blinding description	Both the patient and the researcher are blind to the study. In this way, the patient and the researcher are blind to the saturation or non-saturation of the gelfum with the innovative compound. An unsaturated gelfum is placed on one side of the mouth at the site of the extracted tooth, and the saturated gelfum is placed in place of the opposite tooth in the same extracted jaw and sutured, and the results are measured by me.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

17 shahrivar bvl'd ; dental univesity

City

semnan

Province

Semnan

Postal code

3518794431

Approval date

2021-10-04, 1400/07/12

Ethics committee reference number

IR.SEMUMS.REC.1400.158

Health conditions studied

1

Description of health condition studied

Extraction of wisdom teeth

ICD-10 code

K01

ICD-10 code description

Embedded and impacted teeth

Primary outcomes

1

Description

Reducing pain

Timepoint

Patients are told to report the problem in case of severe pain and discomfort. The VAS form is given to patients to record the amount of pain: 12 and 24 hours after surgery and on 2-3-4-5-6-7 days after surgery.

Method of measurement

Through the VAS chart

2

Description

Inflammation control

Timepoint

The same amount of swelling is measured 42 hours after surgery and on the morning of the 3rd and 7th days after surgery

Method of measurement

Facial width is calculated by marking 5 pink spaces on a piece of yarn and then measuring it with a ruler.
Horizontal distance: The distance between the corner of the lip to the junction of the auricular lobule (Earlobe) on the same side and the piece of thread follow the convexity of the cheek. Vertical: The distance between the outer canthus of the eye to the mandibular angle of

the same side and the piece of thread follow the convexity of the face. Mile: The distance from the corner of the lip to the angle of the mandible on the same side and the piece of floss should follow the possible convexity of the face (swelling after surgery). During these three measurements, the patient lies supine on the unit and the receiver is on the desired side.

3

Description

infection control

Timepoint

In terms of pus, heat and redness in the desired area

Method of measurement

Zero and one technique (zero: no infection and one: infection)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Inserting gelfoam containing amoxicillin, betamethasone and ibuprofen into the silent tooth. Turn until it is impregnated with jelfum to have a longer effect and slower absorption. The patient's tooth is extracted, the saturated gelfum is placed, then two weeks later the opposite tooth is extracted, and the simple unsaturated gelfum is placed as a control, and the results are measured and evaluated.

Category

Treatment - Drugs

2

Description

Control group: Control group: placing unsaturated gelfum inside the extract of the extracted tooth

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan dental university

Full name of responsible person

Atena Afzalimehr

Street address

17 Shahrivar Blvd ; Dental university

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Ava Nikbin

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Pouya Mansourian

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Evaluation of the Effect of an Innovative Combination
Solution Containing: Amoxicillin, Betamethasone and
Ibuprofen on Controlling pain, Swelling and Infection
Caused by Wisdom Tooth Surgery

When the data will become available and for how long

unlimited

To whom data/document is available

unlimited

Under which criteria data/document could be used

unlimited

From where data/document is obtainable

mansourian77pouya@gmail.com

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

unlimited

Comments