

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the efficacy of Curcumin on pain after periodontal flap surgery

Protocol summary

Use of curcumin, pain, age, sex, quadrant and jaw under surgery

Study aim

Evaluation of the effect of Curcumin on pain after periodontal flap surgery in comparison with the control group

Design

Double-blind clinical trial with split mouth design in which each sample participates in 2 phases, once as a case (consumption of Curcumin) and the next time as a control (consumption of Gelofen). (Based on surgery on different quadrants of one jaw) And will be checked in the form of 2 blocks using Excell software. According to the results of the previous study (Maulina et al.), Using the Paired Means Power Analysis option of PASS11 software, considering $\alpha = 0.05$ and $\beta = 0.2$, the standard deviation of the changes is 1.2 and the difference between the means is 1.16 two-way samples were calculated for the study.

Settings and conduct

The appearance and color of gelofen and turmeric capsules are similar and both the operator and the patient are unaware. The first dose is taken 30 minutes before surgery and subsequent doses every 8 hours (for 1 day). Onset of pain with pain based on Numerical Rating Scale (between zero to 10) and after taking the first, second and third dose, the phone is measured and 7 days after the end of medication, the patient referred for surgery on the opposite side of the jaw and by moving the groups, The steps will be repeated exactly.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients requiring periodontal flap surgery and exclusion criteria include allergy to urcumin and Ibuprofen (Gelofen), history of gastrointestinal problems and gastritis, use of anticoagulants, biliary problems and kidney stones.

Intervention groups

Control(Quadrant) group: Two 200 mg gelofen capsules
Case(Quadrant) group: Take two 80 mg turmeric capsules after surgery (every 8 hours) for 1 day.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200929048883N1**

Registration date: **2020-10-18, 1399/07/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-18, 1399/07/27**

Update count: **0**

Registration date

2020-10-18, 1399/07/27

Registrant information

Name

Hesam Hamidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2630 4508

Email address

hesamhamidi75@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Curcumin on pain after periodontal flap surgery

Public title

Evaluation of the efficacy of Curcumin on pain after periodontal flap surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients in need of periodontal flap surgery No history of allergy to Amoxicillin, Curcumin and Ibuprofen (Gelofen) No history of taking any antibiotics, anti-inflammatory and analgesic at least 7 days before surgery No history of gastrointestinal problems and gastritis, use of anticoagulants, biliary problems, kidney stones and gallbladder

Exclusion criteria:

Allergy to Curcumin and Ibuprofen (Gelofen) History of gastrointestinal problems and gastritis Taking anticoagulants Kidney failure Bile problems

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **16**

More than 1 sample in each individual

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

Patients received Curcumin in the first surgery and then 14 days after the last dose of the drug patients will go for surgery on the opposite side of the same jaw and receive Gelofen.

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The same appearance and color of Gelofen and Curcumin capsules to keep participants informed is considered in the study and The surgeon and the person evaluating the outcome are also not aware of the type of medication given.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

کمیته اخلاق در پژوهش‌های زیست پزشکی

Street address

No. 9, 9th Neystan, Pasdaran St

City

tehran

Province

Tehran

Postal code

1946853314

Approval date

2019-10-22, 1398/07/30

Ethics committee reference number

IR.IAU.DENTAL.REC.1398.041

Health conditions studied**1****Description of health condition studied**

Pain after periodontal flap surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The amount of pain

Timepoint

8,16 and 24 hours after surgery

Method of measurement

Questioning the patient by Numerical Rating Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: After surgery, take two 80 mg Curcumin capsules of Sina Curcumin Company (Tehran, Iran) three times a day (every 8 hours) for 1 day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry Islamic Azad University, Building No. 3,
Department of Periodontics

Full name of responsible person

Hesam Hamidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Research and Technology Department

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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

Islamic Azad University

Proportion provided by this source

1

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**

Islamic Azad University

Full name of responsible person

Hesam Hamidi

Position

Dental student

Latest degree

A Level or less

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)**

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

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Your data will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

It can only be used for reviewing and validating the results by journals after submitting them to the said journal

From where data/document is obtainable

Refer to the responsible author at the address and e-mail address mentioned in the article

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

After reviewing the reasons for the request, the documents will be sent to them within a month.

Comments