

# 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

**Street address**

No. 9, 9th Neystan, Pasdaran St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1946853314

**Phone**

+98 21 2630 4508

**Email**

hesamhamidi75@gmail.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Research and Technology Department

**Street address**

No. 9, 9th Neystan, Pasdaran St.

**City**

tehran

**Province**

Tehran

**Postal code**

1946853314

**Phone**

+98 21 2256 4571

**Email**

hesamhamidi75@gmail.com

**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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**Email**

hesamhamidi75@gmail.com

### Person responsible for scientific 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

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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**