

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Assessment of the effect of aspirin on levels of lipoxin A4, interleukin-1 $\beta$ and prostaglandin E2 in periapical exudates: a double blinded randomized clinical trial

#### Protocol summary

##### Study aim

The effect of aspirin on the levels of lipoxin A4, interleukin  $\beta$ 1 and prostaglandin E2 in periapical exudate

##### Design

Clinical trial with control group, parallel, double-blind, randomized

##### Settings and conduct

After anesthesia injection, teeth were isolated with rubber dam. The penetrating chamber with fissure bur. The length of operation after measurement with apex locator is confirmed by radiography. Canal cleaning and shaping is performed according to the protaper system up to F3 size. the canal is washed with 2 ml of normal saline and dried with paper cone. A paper cone No. 40 is inserted into the canal for approximately the length of operation. 3 mm end of it is separated and placed in an ependorf containing PBS ,samples are stored at -70 ° C. After 7 days, sampled similar to the first session, and the canal will be cleaned, shaped and obturated.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with good general health, patients aged 18-45 years, all single root canals, distal mandibular molars and palatal roots of maxillary molars with periapical lesion of >5 mm in diameter, teeth No history of trauma and previous root canal treatment. Exclusion criteria included: 1- non-isolated teeth, 2- presence of periodontal disease, 3- presence of systemic disease, 4-history or presence of other infections, 5-specific physiological conditions, 6-oral ulcers, 7-smokers and Alcohol, 8-gastrointestinal problems, 9-treatment with any drug during the past week, and 10-allergy to salicylates or other non-acute anti-inflammatory drugs.

##### Intervention groups

Patients in the 7 groups receive 7 mg aspirin tablets for 7 days. The placebo was administered similarly to the case group for 7 days.

##### Main outcome variables

Group, Mediator concentration of lipoxin A4, Mediator concentration of Interleukin  $\beta$ 1, Mediator concentration of prostaglandin E2

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191211045702N1**

Registration date: **2019-12-23, 1398/10/02**

Registration timing: **prospective**

Last update: **2019-12-23, 1398/10/02**

Update count: **0**

##### Registration date

2019-12-23, 1398/10/02

##### Registrant information

##### Name

Razieh Salehi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 1086

##### Email address

razieh.salehi@edu.umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Assessment of the effect of aspirin on levels of lipoxin A4, interleukin-1 $\beta$  and prostaglandin E2 in periapical exudates: a double blinded randomized clinical trial

**Public title**

Assessment of the effect of aspirin on periapical inflammation

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with good general health Patients aged 18-45 years All single root, distal root of mandibular molars and palatal root of maxillary molars with periapical lesion of >5 mm in diameter Tooth with no history of trauma and previous root canal treatment

**Exclusion criteria:**

Unable to isolate tooth Presence of periodontal disease Presence of systemic disease History or presence of other infections Specific physiological conditions Oral ulcer Smokers and alcoholics Gastrointestinal problems Treatment with any drug over the past week Sensitivity to salicylates or other non-steroidal anti-inflammatory drugs

**Age**

From **18 years** old to **45 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **30**

More than 1 sample in each individual

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

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization with size 4

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The random process will be performed by someone outside the core research team, and the patient and physician will not know which group the patient is in.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Hamadan University of Medical Sciences

**Street address**

Shahid Fahmideh Ave, dentistry school

**City**

Hamadan

**Province**

Hamadan

**Postal code**

65417838741

**Approval date**

2019-11-23, 1398/09/02

**Ethics committee reference number**

IR.UMSHA.REC.1398.692

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

Apical periodontitis

**ICD-10 code**

K04.5

**ICD-10 code description**

Chronic apical periodontitis

**Primary outcomes****1****Description**

Concentration of inflammatory mediator

**Timepoint**

At baseline and 7 days later

**Method of measurement**

Enzyme-linked immunosorbent kit

**Secondary outcomes**

empty

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

Intervention group: 7 pills of aspirin 80 mg for 7 days

**Category**

Treatment - Drugs

**2**

**Description**

Control group: 7 tablets containing sodium saccharin for 7 days

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Dentistry school

**Full name of responsible person**

Elham Khoshbin

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

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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**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Razieh Salehi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident

**Latest degree**

Medical doctor

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

Results of the main outcome include the concentration of inflammatory mediators in the periapical exudate

### When the data will become available and for how long

after publication of the final article

### To whom data/document is available

En researchers who works in university

### Under which criteria data/document could be used

the data will provide for using in review studies or future clinical trials if cited as regular

### From where data/document is obtainable

r.salehi70510@gmail.com, 09171435936,Razieh Salehi

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

requesting via email that takes maximum one month after receiving the request

### Comments