

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Assessment of the effect of aspirin on levels of lipoxin A4, interleukin-1 β 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 β 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 β 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)

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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 β 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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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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