Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative effect of saffron petal and stigma extract with Ibuprofen in post endodontic pain management

Protocol summary

Summary

(1) Objective: The purpose of this study is to Comparative effect of saffron petal and stigma extract with Ibuprofen on pain control after root canal therapy in vital teeth. (2) Design: This is a randomized triple blind clinical trial. (3)Setting and conduct: Among patients refer to endodontics department of zahedan Faculty of Dentistry whom with moderate to severe pain in a single canal tooth will be selected and randomly divided in 3 groups of petal, stigma extract and Ibuprofen. (4) Participants including major eligibility criteria: Patients should not have any history of allergy to saffron, diabetes, cardiovascular disorders, kidney and liver diseases, blood and hormonal disorders and electrolyte imbalance. According to previous studies and based on sample size formula and possibility of drop out during the study, 60 patients (20 in each group) will be entered in study. (5) Intervention: After treatment each patient in each group will receive a box of 5 similar capsules. They will use 1 capsule exactly after treatment completion and then 6, 12, 24 and 48 hours after treatment. (6) main outcome measures: Patients will record their pain intensity in each time period and finally mean pain intensity will be compared between 3 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051713354N1**
Registration date: **2013-10-29, 1392/08/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-10-29, 1392/08/07

Registrant information

Name
Mojtaba Bazrafshan
Name of organization / entity
Zahedan Univsity of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences, Vice-chancellor for research

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of saffron petal and stigma extract with Ibuprofen in post endodontic pain management

Public title

Comparative effect of saffron extract with Ibuprofen in dental pain management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-vital teeth with one root canal; 2-moderate to severe pain; 3-patients over 18 years old; 4-patients with at least high school education. Exclusion

criteria: 1- teeth with periapical lesions based on radiographic; 2- patients with history of allergy to saffron; 3- patients with history of allergy to NSAID; 4- diabetes mellitus, cardiovascular disorders, kidney and liver diseases, blood and hormonal disorders and electrolyte imbalance; 5- use of analgesics or opioids during 4 hours before treatment; 6- women in pregnancy or breast feeding period.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zahedan University of Medical Sciences Ethics Committee

Street address
Pardis of Zahedan University of Medical Sciences, Khalij-e-Fars Blv, Dr. Hesabi Sq, Zahedan, Iran

City
Zahedan

Postal code

Approval date
2013-05-12, 1392/02/22

Ethics committee reference number
92-184

Health conditions studied

1

Description of health condition studied
Post-treatment pain after root canal therapy

ICD-10 code
k04

ICD-10 code description
Diseases of pulp and periapical tissues

Primary outcomes

1

Description
Pain intensity

Timepoint
0 - 6 - 12 - 24 and 48 hours after root canal treatment

Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Lack of pain intensity

Timepoint
0-6-12-24-48

Method of measurement
Visual Analog Scale(VAS)

Intervention groups

1

Description
saffron stigma extract with dose of 10 mg in each pink opaque capsule in 0, 6, 12, 24, 48 h after treatment

Category
Treatment - Drugs

2

Description
400 mg ibuprofen in each pink opaque capsule in 0, 6, 12, 24, 48 h after treatment

Category
Treatment - Drugs

3

Description
saffron petal extract with dose of 10 mg in each pink opaque capsule in 0, 6, 12, 24, 48 h after treatment

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Zahedan Faculty of Dentistry

Full name of responsible person
Mojtaba Bazrafshan

Street address

Eastern Azadegan St, Zahedan Faculty of Dentistry, Zahedan, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences, Vice-chancellor for research

Full name of responsible person

Dr. Mohsen Taheri

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Pardis of Zahedan Univsity of Medical Sciences, Khalij-e-Fars Blv, Dr. Hesabi Sq, Zahedan, Iran

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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

Zahedan University of Medical Sciences, Vice-chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mojtaba Bazrafshan

Position

Dentistry Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty