Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of saffron (Crocus sativus) on pain control after root canal therapy in teeth with vital pulps

Protocol summary

Summary

The purpose of this study is to evaluate the effect of saffron on pain control after root canal therapy in vital teeth. This is a randomized triple blind placebo control clinical trial. Among patients refer to endodontics department of Tehran Faculty of Dentistry whom with moderate to severe pain in a single canal tooth will be selected and randomly divided in 2 groups of saffron and placebo. 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, 36 patients (18 in each group) will be entered in study. After treatment each patient in each group will receive a box of 8 similar capsules. They will use 1 capsule exactly after treatment completion and then each 6 hours up to 48 hours. Patients will record their pain intensity in each time period and finally mean pain intensity will be compared between 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204039367N1**
Registration date: **2012-04-16, 1391/01/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-04-16, 1391/01/28

Registrant information

Name

Kaveh Oloumi

Name of organization / entity

Department of Endodontics, Faculty of Dentistry, Tehran University 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

2012-04-20, 1391/02/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of saffron (Crocus sativus) on pain control after root canal therapy in teeth with vital pulps

Public title

Effect of saffron on dental pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: vital teeth with one root canal and moderate to severe pain and patients over 18 years old with at least high school education Exclusion criteria: teeth with periapical lesions; patients with history of allergy to saffron; diabetes mellitus, cardiovascular disorders, kidney and liver diseases, blood and hormonal

disorders and electrolyte imbalance; women in pregnancy or breast feeding period and use of analgesics or opioids during 4 hours before treatment.

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: **36**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zahedan University of Medical Sciences Ethics Committe

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

City
Zahedan

Postal code
98167-43463

Approval date
2011-12-03, 1390/09/12

Ethics committee reference number
90-1774

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
Every 6 hours after treatment completion up to 48 hours

Method of measurement
Visual Analog Scale(VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: saffron with dose of 100 mg in each capsule every 6 hours up to 48 hours (400 mg/day)

Category
Treatment - Drugs

2

Description
Control:starch with dose of 100 mg in each capsule every 6 hours up to 48 hours (400 mg/day)

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of endodontics, Faculty of Dentistry, Tehran University of Medical Sciences

Full name of responsible person
Dr. Kaveh Oloomi

Street address
Department of Endodontics, Tehran Faculty of Dentistry, North Karegar St., Tehran.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Scienves, Vice-chencellor for research

Full name of responsible person
Dr. Mohsen Taheri

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

City
Zahedan
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 Scienves, Vice-chencellor 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
Endodontics Department- Faculty of Dentistry- Tehran University of Medical Sciences
Full name of responsible person
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Position
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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