

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 42794445

Email address

bolhari@tums.ac.ir

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
pulp

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 Committee

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 Sciences, Vice-chancellor 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 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
Endodontics Department- Faculty of Dentistry- Tehran University of Medical Sciences

Full name of responsible person
Dr. Kaveh Oloomi

Position
Assistant Professor/Endodontist

Other areas of specialty/work
Street address
Endodontics Department-Tehran Faculty of Dentistry- North Karegar St.-Tehran

City
Tehran

Postal code
1439955991

Phone
+98 21 8835 1173

Fax
Email
koloomi@yahoo.com

Web page address
<http://dentistry.tums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Endodontics Department- Faculty of Dentistry- Tehran University of Medical Sciences

Full name of responsible person
Dr. Kaveh Oloomi

Position
Assistant Professor/Endodontist

Other areas of specialty/work

Street address

Endodontics Department-Tehran Faculty of Dentistry- North Karegar St.-Tehran

City

Tehran

Postal code

1439955991

Phone

+98 21 8835 1173

Fax

+98 88497400

Email

koloomi@yahoo.com

Web page address

<http://dentistry.tums.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity

Endodontics Department- Faculty of Dentistry- Tehran University of Medical Sciences

Full name of responsible person

Dr. Kaveh Oloomi

Position

Assistant Professor/Endodontist

Other areas of specialty/work

Street address

Endodontics Department-Tehran Faculty of Dentistry- North Karegar St.-Tehran

City

Tehran

Postal code

1439955991

Phone

+98 21 8835 1173

Fax

+98 88497400

Email

koloomi@yahoo.com

Web page address

<http://dentistry.tums.ac.ir>

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