

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative evaluation of post-endodontic pain following root canal therapy by two different rotary instrumentation systems : Reciproc & Oneshape

Protocol summary

Summary

Objectives: extrusion of infected dentin into the periapical tissue has been suggested as a major source of pain after endodontic treatment. Although debris extrusion is an inevitable finding even when instrumentation is limited to the confines of the canal, different armamentarium seem to be associated with different amounts of debris extrusion. Studies on the effect of various rotary files on post-endodontic pain are very few and have yielded conflicting results with some favoring full-sequence and others leaning towards reciprocal rotary systems. This study aims at assessing the intensity of post-endodontic pain following two different rotary systems, Reciproc and One Shape.

Methods: in this single-blind, parallel-grouped randomized clinical trial a total of 150 otherwise healthy patients aged between 20 to 50 years old with a pulpal status of irreversible pulpitis for one tooth in the upper or lower molar region were analyzed. A clinician performed the endodontic treatment in three groups, a control group instrumented using K-files, a group instrumented using Oneshape and a third group with instrumentation performed using Reciproc rotary systems.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042227519N1**
Registration date: **2016-05-05, 1395/02/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-05, 1395/02/16

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Zahedan University Of Medical Sciences

Expected recruitment start date

2015-10-22, 1394/07/30

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of post-endodontic pain following root canal therapy by two different rotary instrumentation systems : Reciproc & Oneshape

Public title

Comparative evaluation of post-endodontic pain following root canal therapy by two different rotary instrumentation systems

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the otherwise healthy patients were aged between 20 to 50 years old with a pulpal status of irreversible pulpitis for one tooth in the upper or lower molar region. Exclusion criteria: previous endodontic treatment; a history of drug intake including corticosteroids; opioids and NSAIDs in the previous 12 hours; pregnancy; complicated anatomy (curves greater than 25 degrees); calcifications; internal & external resorption; open apices; periodontal disease; swelling & abscess; presence of periapical lesions; sensitivity to percussion and lack of occlusal contact.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

ClinicalTrials.gov

Secondary trial Id

NCT02621034

Registration date

2015-11-29, 1394/09/08

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Pardis university- Dr Hesabi Square- Zahedan-Iran

City

Zahedan

Postal code

43463-98167

Approval date

2016-04-13, 1395/01/25

Ethics committee reference number

IR.ZAUMS.REC 7198

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Pain

Timepoint

6 hours after treatment, 12 hours after treatment, 24 hours after treatment, 48 hours after treatment and 72 hours after treatment

Method of measurement

Visual Analogue Scale questionnaire

Secondary outcomes

1

Description

Swelling

Timepoint

6 hours after treatment, 12 hours after treatment, 24 hours after treatment, 48 hours after treatment and 72 hours after treatment

Method of measurement

Clinical assessment

Intervention groups

1

Description

Control group : using K-files via the stepback technique

Category

Treatment - Surgery

2

Description

Reciproc group : using the Reciproc system

Category

Treatment - Surgery

3

Description

Oneshape group : using the Oneshape system

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan dental school

Full name of responsible person

Seyed Roholla Havaei

Street address

Zahedan dental school

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ministry of research and development

Full name of responsible person

Ghazale Ashrafzadeh

Street address

Ministry of research and development- Zahedan- Iran

City

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

ministry of research and development

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

Eshagh Ali Saberi

Position

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Web page address

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