Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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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

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Zahedan

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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
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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

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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