Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of clinical and antimicrobial efficacy of 2% IKI and 2.5% sodium hypochlorite irrigants in infected root canals- An in vivo study

Protocol summary

Summary

It is believed that effective debridement of the root canal system prior to filling with aid of chemical irrigants is the key to long-term success of endodontic therapy. The purpose of this study is to compare the antibacterial activity of 2.5% NaOCl and 2% IKI solutions as intracanal disinfectant in infected root canals during one-visit endodontic treatment procedure.For this purpose, thirty single-rooted teeth with necrotic pulps and periapical lesion will be selected acording to the following inclusion/exclusion criteria. Patients who received antibiotic therapy within the past 3 months will be excluded as well as teeth with extensive caries or fractures of the root/crown, teeth with a history of previous endodontic treatment, and cases showing periodontal pockets over 4 mm depth. Possible complications/risks will be explained to the patients and informed consents will obtaine before starting the treatment. Since the following up of treated patients is also crucial for accurate evaluation of the efficiency of any employed antimicrobial irrigants; the aim of the second stage of the study is to compare and evaluate the healing of treated teeth of those patients after a period of thirty months The selected thirty single-rooted teeth will divide in to two groups randomly. In group I, 2.5% NaOCl is an irrigant during instrumentation and in group II; canals will initially irrigate with sterile saline during biomechanical preparation and then expose to a 5-minute final irrigation with 2% IKI. Bacterial samples will take before treatment (S1), and at the end of treatment (S2) and the antimicrobial efficacy of each experimental group will be evaluated.After 30 months, patients will recall and examine clinically and radiographically. Presence of sinus tract, swelling, mobility, tenderness to percussion or palpation and probing depth greater than the baseline measures will be recorded by an independent investigator.Post-operative and follow-up images will be evaluated randomly in a dark room with aid of an X-ray view box and magnifying glass and will be given a periapical score according to PAI scoring system.The outcome will be assessed in two ways.First, the changes in PAI score from base line to the follow-up evaluation will be assessed. Second, the dichotomous variables as “healed” or “not healed” will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903264196N1**
Registration date: **2013-01-19, 1391/10/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-01-19, 1391/10/30

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2009-12-31, 1388/10/10

Expected recruitment end date

2010-06-01, 1389/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical and antimicrobial efficacy of 2% IKI and 2.5% sodium hypochlorite irrigants in infected root canals- An in vivo study

Public title

Clinical & antimicrobial effect of iodine potassium iodide

Purpose

Treatment

Inclusion/Exclusion criteria

Only teeth with necrotic pulps as confirmed by negative response to sensitivity pulp tests were included in this study. Patients who received antibiotic therapy within the past 3 months were excluded from the study. Teeth with extensive caries or with fractures of the root/crown and with history of previous endodontic treatment did not consider in the study. Besides, cases showing periodontal pockets over 4 mm depth were also excluded.In the second phase,presence of sinus tract, swelling, mobility, tenderness to percussion or palpation and probing depth greater than the baseline measures will be recorded by an independent investigator and will serve as exclusion criteria

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

خیابان زند-ساختمان مرکزی دانشگاه علوم پزشکی شیراز

City

Shiraz

Postal code

Approval date

2009-12-22, 1388/10/01

Ethics committee reference number

98-5109

Health conditions studied

1

Description of health condition studied

Chronic apical periodontitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bacterial load reduction in post-treatment samples in comparison to initial samples

Timepoint

At the end of trearment session

Method of measurement

Microbial colony forming unit(CFU)

Secondary outcomes

1

Description

Any Change in periapical status from the baseline and presence or absence of clinical sign& symptoms after 30-months

Timepoint

30-months

Method of measurement

Clinical and radiographical evaluation of treated patient after 30-months

Intervention groups

1

Description

Intervention group: After first antimicrobial sampling upon access (S1), in this group irrigation was carried out with normal saline. Two milliliters of this solution were used to irrigate the canals after each instrument (10mL overall).Each canal was flushed with 2% IKI solution as final rinse for a period of 5 minutes. After inactivation of IKI with 2mL 5% sodium thiosulfate followed by 2mL normal saline, the second microbial sampling (S2) was

performed.Subsequently, the canals were filled with gutta-percha and Tubli-Seal sealer (ZOE-based; SybronEndo, Orange, CA, USA) using cold lateral compaction technique. The tooth was temporized and permanent restoration was planned at the next visit.Moreover, the patients will follow-up after 30 months to evaluate the periapical healing of the teeth by clinical and radiological examinations.

Category

Treatment - Other

2

Description

Positive control group: After the first antimicrobial sampling upon access (S1), in this group irrigation was performed with 2 mL 2.5% NaOCl after each instrument (10mL overall).After instrumentation was completed, the canals were flushed with 2 mL 5% sodium thiosulfate followed by 2 mL normal saline and second microbial sampling (S2) was achieved by using 3 sterile paper cones. Subsequently, the canals were filled with gutta-percha and Tubli-Seal sealer (ZOE-based; SybronEndo, Orange, CA, USA) using cold lateral compaction technique. The tooth was temporized and permanent restoration was planned at the next visit. Moreover, the patient will follow-up 30 months after treatment to monitor the healing of periapical lesion by clinical and radilogical examinations.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic at shiraz Dental School

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz university of Medical Scienced

Full name of responsible person

Dr.Poostforoosh

Street address

Cenral University building،Zand st

City

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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

Shiraz university of Medical Scienced

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

Faculty of Dentistry,Shiraz Universsity of Medical Sciences

Full name of responsible person

Abbas Abbaszadegan

Position

Assistant professor

Other areas of specialty/work

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Person responsible for scientific 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