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Assessment of the relationship between different irrigation activation techniques and postoperative pain and tenderness to percussion

Submission date
16/01/2018

Recruitment status
No longer recruiting

Registration date
25/01/2018

Overall study status
Completed

Last Edited
24/01/2018

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Root canal treatment is a dental procedure used to treat infection at the centre of a tooth (the root canal system). Irrigation activation systems are used to flush out the root canal system. The aim of this study is to compare the pain and tenderness experienced by patients after undergoing different irrigation activation techniques.

Who can participate?
Healthy volunteers aged 18-60

What does the study involve?
The participants' premolar teeth are randomly allocated to undergo one of five irrigation activation techniques: conventional irrigation, manual dynamic irrigation, passive ultrasonic irrigation, EndoVac irrigation, and photon-initiated photoacoustic streaming irrigation. The treatment is completed in a single session. Spontaneous pain and tenderness to percussion are assessed after 6, 24 and 48 hours.

What are the possible benefits and risks of participating?
The techniques are suited to clinical standards. The treatment does not involve any risk.

Where is the study run from?
İzmir Katip Çelebi University (Turkey)

When is the study starting and how long is it expected to run for?
January 2015 to October 2015

Who is funding the study?
İzmir Katip Çelebi University (Turkey)

Who is the main contact?
Gokhan Saygili

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16-01-1618

Study information

Scientific Title
Assessment of the relationship between different irrigation activation techniques and postoperative pain and tenderness to percussion

Study objectives
The aim of this study was to compare the postoperative pain and tenderness to percussion experienced by patients who had been subject to contemporary irrigation activation techniques involving different mechanisms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of İzmir Katip Çelebi University of Clinical Sciences, 12/11/2014, ref: 177

Study design
Randomised controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Root canal treatment (endodontics)

Interventions
Vital pulp mandibular premolar teeth (single canal) were selected from either asymptomatic irreversible pulpitis such as deep dentine caries and secondary caries, or normal pulps that were referred for prosthetic reasons. 20 mandibular premolars were randomised to one of five groups: conventional irrigation (CI), manual dynamic irrigation (MDI), passive ultrasonic irrigation (PUI), EndoVac irrigation (EV) and photon-initiated photoacoustic streaming irrigation (PIPSI) techniques were applied as the means of final irrigation of the root canals. The final irrigation was performed with the five different techniques after the canals were enlarged. The endodontic treatment of the teeth was completed in a single session. The spontaneous pain and tenderness to percussion analyses were performed after 6, 24 and 48 hours. A visual analogue scale (VAS) was used to measure spontaneous pain and tenderness to percussion. The statistical analyses were performed using the Kruskal-Wallis and Mann-Whitney U tests.

The irrigation protocols are detailed in terms of both quantity and time. Concentrations of 17% EDTA and 2.5% NaOCl were used in all the groups.

Conventional irrigation (CI)
An irrigation cannula was adjusted 1 mm coronal to the working length. During the irrigation, the cannula was moved 2 mm up and down in this area. As intracanal irrigation, both 2 ml/min EDTA and 5 ml/min NaOCl were used. In this group, 2 ml EDTA and 5 ml NaOCl were used.

Manual dynamic irrigation (MDI)
The location of the injector and the quantity/time of the irrigation were the same as in the CI group. During the activation, a gutta-percha cone that was one size smaller than the master gutta-percha cone (Micro Mega, Besancon, France) was selected. The cone was adjusted 1 mm coronal to the working length and it was activated at a rate of 100 push-pull strokes per minute. In this group, 2 ml EDTA and 5 ml NaOCl were used.

Passive ultrasonic irrigation (PUI)
The location of the injector and the quantity/time of the irrigation were the same as in the CI group. While the ultrasonic (Acteon Satelec, France) activation’s sixth power setting was applied, a specific ultrasonic file (size 15/.02 taper) (Varios U files, Nakanishi, Japan) was placed 1-4 mm short of the working length and then moved up and down. While the ultrasonic activation was

carried out, it was ensured that there was always solution in the canal. If there was a decrease in the intracanal solution, more solution was irrigated into the canal. In this group, 2 ml EDTA and 5 ml NaOCl were used.

EndoVac irrigation (EV)
Using an MDT, NaOCl was replenished as the irrigant in the pulp chamber after each rotary file. When irrigating with an MDT, both EDTA and NaOCl were used at 12 ml/min. Following complete shaping, a macrocannula was used in the canal with NaOCl for 30 seconds. During aspiration, the macrocannula was moved up and down until it could reach the working length. The microcannula was withdrawn 1 mm from the full working length. To prevent jams in the apical region during aspiration with the microcannula, the movements of air bubbles in the hose were observed. In this group, 2 ml EDTA and 18 ml NaOCl were used.

Photon-induced photoacoustic streaming irrigation (PIPSI)
An Er:YAG laser (Fidelis AT Fotona, Ljubljana, Slovenia) was used and a 14 mm long, 300 µm quartz laser tip was applied with 0.3 W (15 Hz and 20 mJ per pulse). As the laser system was worked, the water and air were turned off. The patient, physician and assistant all wore protective glasses. This group was irrigated with activation at the same time. When irrigating with PIPSI, both EDTA and NaOCl were used at 4 ml/min. In this group, 2 ml EDTA and 2 ml NaOCl were used.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain measured using a visual analogue scale (VAS) from 0 to 10 (0 = no pain, 10 = extremely strong, maximum pain) after 6, 24 and 48 hours

Secondary outcome measures
Percussion assessments performed using the handle of a mirror by the same clinician using the same force and the same posture after 6, 24 and 48 hours

Overall study start date
05/01/2015

Completion date
30/10/2015

Eligibility

Key inclusion criteria
1. Age 18-60
2. Male or female

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit

18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
3 patients (20 mandibular premolars)

Key exclusion criteria
1. Systemic disease
2. Non vital pulpa
3. Pain
4. Patients who cannot wear rubber dam

Date of first enrolment
16/02/2015

Date of final enrolment
18/02/2015

Locations

Countries of recruitment
Türkiye

Study participating centre
İzmir Katip Çelebi University
Faculty of Dentistry
35020

Sponsor information

Organisation
İzmir Katip Çelebi University

Sponsor details
Scientific research projects unit
Cigli
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Sponsor type
University/education

Website
http://ikc.edu.tr/

ROR
https://ror.org/024nx4843

Funder(s)

Funder type
University/education

Funder Name
İzmir Katip Çelebi University

Results and Publications

Publication and dissemination plan
This is a thesis work. This study is also aimed at publishing and distributing to the international field as soon as possible.

Intention to publish date
24/04/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Gokhan Saygili.

IPD sharing plan summary
Available on request