ISRCTN14290358 https://doi.org/10.1186/ISRCTN14290358

Assessment of the procedure duration and success of alternative emergency treatments for patients with painful dental pulp disease

Submission date
07/06/2017

Recruitment status
No longer recruiting

Registration date
08/06/2017

Overall study status
Completed

Last Edited
15/03/2018

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The dental pulp which is the soft tissue inside the root canal, can become inflamed (swollen) due to a variety reasons, such as deep decay, traumatic injuries, gum disease and repeated dental procedures on the tooth. If pulp inflammation is left untreated, it can cause pain. Ideally, emergency treatment for painful pulp disease involves removing all of the inflamed or infected pulp from the root canals (total pulpectomy), cleaning the inside of the root canal, then filling and sealing the space temporarily. However, root canal emergencies due to painful pulp disease require unscheduled office visits, cause inconvenience, and disrupt routine schedules. In such cases, the time required to intervene is often an issue. Moreover, emergency root canal procedures, like other dental treatments, may be interrupted by unexpected and unfavourable “procedural errors" due to time constraints. Many such problems can be avoided by applying acceptable, simplified treatment technique that will relieve pain quickly and efficiently in cases of painful pulp disease. Accordingly, the removal of a portion of the pulp within the tooth crown only (pulpotomy) or removal of the pulp tissue from the crown and the largest root canal (partial pulpectomy) has been recommended for emergency treatment of painful pulp disease (symptomatic irreversible pulpitis). The aim of this study therefore is to find out whether performing pulpotomy or partial pulpectomy can relieve pain effectively and reduce the procedure duration.

Who can participate?
Adults with dental pain who have been diagnosed with painful pulp disease.

What does the study involve?
Participants are asked to join this study while they are at the emergency dental service. Participants are randomly allocated to one of three groups. Those in the first group receive total pulpectomy, which involves removing all of the pulp tissue. Those in the second group receive partial pulpectomy, which involves removing some of the pulp tissue. Those in the third group receive pulpotomy, which involves removing specific pulp tissue. Participants are asked to record pain intensity using a scale that ranged from no pain to unbearable pain and history of pain upon chewing and thermal (hot and cold) at the beginning of the study. Once a procedure is

finished, the patient is prescribed pain killers. Participants are asked to complete questionnaires about daily pain relief requirements and about clinical symptoms (pain intensity, chewing sensitivity, and hot and cold sensitivity) after the anaesthetic (numbing injection) has worn off and then one, three and seven days following treatment. All participants are scheduled for root canal treatment completion at appropriate intervals after the research period.

What are the possible benefits and risks of participating?
Participants benefit from having the costs of their treatments covered. There are no notable risks involved with participating.

Where is the study run from?
Baskent University Faculty of Dentistry (Turkey)

When is study starting and how long is it expected to run for?
February 2016 to April 2017

Who is funding the study?
Baskent University Research Fund

Who is the main contact?
1. Dr Emel Olga Onay (scientific)
eonay@baskent.edu.tr
2. Dr Birgul Eren (scientific)
birguleren85@hotmail.com
3. Professor Mete Ungor (scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Emel Olga Onay

ORCID ID
http://orcid.org/0000-0001-5800-8871

Contact details
Department of Endodontics
Faculty of Dentistry
Baskent University
82. sok. No. 26, Bahcelievler
Ankara
Türkiye
06490
+90 312 203 0000
eonay@baskent.edu.tr

Type(s)
Scientific

Contact name
Dr Birgul Eren

Contact details
Department of Endodontics
Faculty of Dentistry
Baskent University
82. sok. No. 26
Bahcelievler
Ankara
Türkiye
06490
+90 312 203 0000
birguleren85@hotmail.com

Type(s)
Scientific

Contact name
Prof Mete Ungor

Contact details
Department of Endodontics
Faculty of Dentistry
Baskent University
82. sok. No. 26
Bahcelievler
Ankara
Türkiye
06490

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
D-KA16/08

Study information

Scientific Title
Assessment of the procedure duration and efficacy of pulpotomy and partial pulpectomy in comparison with total pulpectomy for patients with symptomatic irreversible pulpitis: a randomized clinical trial

Study objectives

Performing pulpotomy or partial pulpectomy aimed at relieving pain effectively and reducing the procedure duration in emergency cases with symptomatic irreversible pulpitis. This in turn will maintain the clinicians' ability to intervene in the clinical setting of a busy practice with limited time for emergencies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Baskent University Institutional Review Board and Ethics Committee, 15/04/2016, ref: D-KA16 /08.

Study design
Single-blinded single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Symptomatic irreversible pulpitis

Interventions
Participants are randomised to one of three groups using sealed envelope randomisation.

Intervention group 1: Participants undergo pulpotomy treatment during a single-visit. This involves removing the coronal pulp tissue with a sterile curette, which followed by achieving haemostasis using dry cotton pellets and applying light pressure, and placing a temporary filling after induction of an adequate anaesthesia and completion of the cavity preparation. The total time per pulpotomy treatment is recorded for each tooth, with timing initiated once access cavity preparation is complete.

Intervention group 2: Participants undergo partial pulpectomy treatment during a single-visit. This involves removing the pulp tissue from the pulp chamber and the largest canal (i.e. the palatal canals of maxillary molars and distal canals of mandibular molars) with sterile curettes and barbed broaches, which followed by working length determination, cleaning and initial shaping procedures, dressing, and placing a temporary filling after induction of an adequate

anaesthesia and completion of the cavity preparation. The total time per partial pulpectomy treatment is recorded for each tooth, with timing initiated once access cavity preparation is complete.

Control group: Participants undergo conventional total pulpectomy treatment during a single-visit. This involves removing the entire pulp tissue from the tooth with barbed broaches, which followed by working length determination, cleaning and initial shaping procedures, dressing, and placing a temporary filling after induction of an adequate anaesthesia and completion of the cavity preparation. The total time per total pulpectomy treatment is recorded for each tooth, with timing initiated once access cavity preparation is complete.

Follow up takes place once the anaesthetic effect has disappeared (Day 0), and subsequently on days 1, 3, and 7 post-procedure and involves recording three pain measures: postoperative pain intensity (visual analogue score), pain upon chewing (absent/present), and pain upon thermal stimulus (absent/present) on the questionnaires by the patients. Additional follow up takes place from the time the anaesthetic effect wore off to the end of that day (Day 0), and on each subsequent day of the first postoperative week and involves recording the frequencies and amounts of analgesic use on the questionnaires by the patients.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Pain intensity is measured using a visual analogue scale (VAS) at baseline, after the anaesthetic effect has disappeared (Day 0) and 1, 3, and 7 days post-treatment
2. Pain relief is assessed by reviewing “Clinical Evaluation Questionnaire” forms and calculating the changes in pain intensity between each reporting time points (baseline-Day 0; baseline- Day 1; baseline-Day 3; baseline-Day 7; Day 0-Day 1; Day 0-Day 3; Day 0-Day 7; Day 1-Day 3; Day 1-Day 7; Day 3-Day 7)
3. Total time per procedure per tooth is expressed in minutes during surgery

Secondary outcome measures
1. Daily analgesic requirements from the time the anaesthetic wore off (Day 0) throughout the 7 days post-surgery is measured by reviewing “Clinical Evaluation Questionnaire” forms and calculating the frequencies and amounts of analgesic use per patient at Day 0, and 1, 2, 3, 4, 5, 6, and 7 days post-treatment
2. Proportion of patients with thermal sensitivity is measured by reviewing “Clinical Evaluation Questionnaire” forms and calculating the percentage at baseline, after the anaesthetic effect has disappeared (Day 0) and 1, 3, and 7 days post-treatment
3. Thermal sensitivity relief is assessed by reviewing “Clinical Evaluation Questionnaire” forms and calculating the changes in prevalence of thermal sensitivity between each reporting time points (baseline-Day 0; baseline- Day 1; baseline-Day 3; baseline-Day 7; Day 0-Day 1; Day 0-Day 3; Day 0-Day 7; Day 1-Day 3; Day 1-Day 7; Day 3-Day 7)
4. Proportion of patients with chewing sensitivity is measured by reviewing “Clinical Evaluation Questionnaire” forms and calculating the percentage at baseline, after the anaesthetic effect has disappeared (Day 0) and 1, 3, and 7 days post-treatment
5. Chewing sensitivity relief is assessed by reviewing “Clinical Evaluation Questionnaire” forms and calculating the changes in prevalence of chewing sensitivity between each reporting time points (baseline-Day 0; baseline- Day 1; baseline-Day 3; baseline-Day 7; Day 0-Day 1; Day 0-Day 3; Day 0-Day 7; Day 1-Day 3; Day 1-Day 7; Day 3-Day 7)

Overall study start date
15/02/2016

Completion date
04/04/2017

Eligibility

Key inclusion criteria
1. Aged between 18 and 60 years
2. Male or female
2. Acute dental pain in posterior maxillary or mandibular molar teeth
4. Diagnosed with symptomatic irreversible pulpitis with or without symptomatic apical periodontitis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
66

Key exclusion criteria
1. History of American Society of Anesthesiologists (1963) III-VI status
2. Pregnancy or nursing
3. Mental disability
4. History of allergy to nonsteroidal anti-inflammatory drugs, and analgesic treatment during the 12 hours prior to presentation
5. If the subject tooth has moderate or severe marginal periodontitis, horizontal or vertical fractures, internal or external root resorption, root canal calcification, or a nonrestorable crown defect
6. If an opposing and/or neighbouring tooth has defective restorations, deep caries, moderate or severe marginal periodontitis, wear, or history of recent tooth preparation.

Date of first enrolment
20/04/2016

Date of final enrolment
25/01/2017

Locations

Countries of recruitment
Türkiye

Study participating centre
Baskent University, Faculty of Dentistry
82. sok. No. 26
Bahcelievler
Ankara
Türkiye
06490

Sponsor information

Organisation
Baskent University

Sponsor details
Taskent Caddesi 77
Sokak No: 11
Bahcelievler
Cankaya
Ankara
Türkiye
06490
+90 312 212 9065
arastirma@baskent.edu.tr

Sponsor type
University/education

Website
http://tip.baskent.edu.tr/kw/genel.php?birim=600&id=2486&menu_id=19

ROR
https://ror.org/02v9bqx10

Funder(s)

Funder type
University/education

Funder Name

Baskent Üniversitesi

Alternative Name(s)
Baskent University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Türkiye

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
15/09/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Emel Olga Onay (eonay@baskent.edu.tr) or Dr Birgul Eren (birguleren85@hotmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018		Yes	No