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Alleviation of acute dental pain: A study comparing two emergency treatment procedures

Submission date
18/09/2017

Recruitment status
No longer recruiting

Registration date
19/09/2017

Overall study status
Completed

Last Edited
19/09/2017

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
In dental practices, patients frequently complain of pain from a tooth. An emergency treatment for this comprises of complete disinfection of the root canal system and sometimes an additional antibiotic treatment. Several studies show good results for an emergency treatment including removal of the superficial parts of the tissue in teeth still containing blood supply and thus no infection. A similar emergency treatment, where the blood supply is lacking and the root canals are infected, is the removal of the superficial parts but then leaving infected tissue in the root canals. This is a crucial difference which may have a negative impact on pain relief. The purpose of emergency treatment for patients suffering from toothache is to reduce the pain to an acceptable level and preferably to remove the causative factors. Regardless of whether or not the clinic has times reserved for such patients, it is important to provide the emergency treatment as efficiently as possible. There is little scientific evidence to support the effectiveness of the latter procedure. The aim of this study is to examine if either treatment approach provides pain relief in patients.

Who can participate?
Adults aged 18 and older who have gum disease.

What does the study involve?
Participants receive a questionnaire with questions about their pain and if they have taken any pain medication before the examination. After accepted to take part in the study, participants are randomly allocated to one of two suggested emergency treatments. Those in the first treatment have a rubber cover is placed around the tooth, and then the root canal/s is/are thoroughly cleaned before the tooth is temporary filled. This treatment takes longer than the second method, where only all tissue in the crown of the tooth is removed before the tooth is temporary filled. Those in the second treatment receive a return visit within two weeks to get the entire root system of the tooth cleaned as described above. For both treatments, participants are contacted by phone within 3-5 days after the first treatment to rate their pain again. Regardless of what treatment is being performed, the patient is informed that he/she must undergo further treatment at a later date, which is permanent.

What are the possible benefits and risks of participating?
Participants may benefit from reduction in symptoms. One issue raised in combination with removal only of the superficial tissue in the tooth, is that leaving infected tissue in the root canals might potentially increase prescription of antibiotics. As removal only of the superficial tissue in the tooth does not remove infection in the root canals, there is a potential risk of further spread of infection. It is therefore decided to exclude patients with systemic involvement (fever, swelling), in order to minimize any risk of aggravation of the condition. However the patients are encouraged to get in contact with the clinic in case of an aggravation.

Where is the study run from?
Malmö University (Sweden)

When is the study starting and how long is it expected to run for?
September 2011 to August 2017

Who is funding the study?
Malmö University (Sweden)

Who is the main contact?
Dr Eva Wolf
eva.wolf@mah.se

Contact information

Type(s)
Scientific

Contact name
Dr Eva Wolf

ORCID ID
https://orcid.org/0000-0001-7425-1038

Contact details
Department of Endodontics
Faculty of Odontology
Malmö University
Malmö
Sweden
205 06
+46406657000
eva.wolf@mah.se

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Acute dental pain from localized apical periodontitis: A prospective randomized study comparing two emergency treatment procedures with the outcome measure pain relief

Study objectives
Regardless of treatment approach, either procedure would achieve clinically acceptable pain relief in the majority of patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board at Lund University approved the stud, 21/03/2013, ref: Diary Number 2013/167)

Study design
A single center randomised controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Symptomatic apical periodontitis

Interventions
Participants are randomised using a randomisation chart created in Microsoft Office Excel 2007 with numbers from 1–1000. This is used to allocate the patients to a treatment group: complete chemo-mechanical disinfection of the root canal system (CMD) (even numbers) or the removal of necrotic tissue from the pulp chamber but without instrumentation of the root canals (RNT) (odd numbers). The randomisation is carried out by the operator immediately after the diagnosis had been made and the patient had agreed to participate. No steps are taken to conceal the sequence until interventions are assigned.

Control group: Complete chemo-mechanical disinfection of the root canal system (Control)
Intervention group: Removal of necrotic tissue from the pulp chamber, i.e. without instrumentation of the root Canals

The examinations and the subsequent emergency treatments are undertaken by undergraduate students under the supervision of a specialist or resident in endodontics, or else by the specialist /resident himself or herself at the emergency clinic. Initial registration included the pre-operative pain rating on NRS and any intake of analgesics: none, peripheral or central. Non steroidal anti-inflammatory drugs, acetylsalicylic acid and paracetamol are registered as peripheral analgesics and opioids are registered as central drugs. Any caries are completely excavated and access are prepared in order to expose the orifices of all the root canals. The complete chemo-mechanical disinfection treatment is undertaken under rubber dam, isolating the working area from the oral fluids. The tooth and clamp are disinfected with a 30% solution of hydrogen peroxide, while the entire field of operation, including the tooth, clamp, and rubber dam, is disinfected with 0.5% chlorhexidine alcohol. The root canals are cleaned and shaped

using the crown-down concept with K3 rotary instrumentation and/or manual instruments following the ISO standardization, to a size at which necrotic tissue and infected dentin could be adequately removed, i.e. at least ISO35, or two sizes larger than the first apically binding file. The root canals are irrigated with 0.5% buffered sodium hypochlorite solution and 15% ethylenediaminetetraacetic acid solution. After chemo-mechanical disinfection, all the teeth are dressed with calcium hydroxide and sealed with a temporary dressing of zinc oxide-eugenol cement (ZOE), covered by glass ionomer cement.

The removal of necrotic tissue in the pulp chamber treatment is carried out without rubber dam. Necrotic and infected tissue is flushed out of the pulp chamber with non-sterile water. The teeth are then sealed with ZOE and a glass ionomer cement. A new appointment was scheduled at the Department of Endodontics within two weeks of the emergency treatment, for complete chemo-mechanical disinfection of the tooth.

For both treatments, participants are contacted by phone within 3-5 days after the first treatment to rate their pain again. Regardless of what treatment is being performed, the patient is informed that he/she must undergo further treatment at a later date, which is permanent.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain relief is measured using telephone calls to the patient (patients were then asked to grade their current post-operative pain levels on the same scale; a grading of NRS <4 was considered to represent adequate pain relief) at days three to five days after treatment.

Key secondary outcome(s))
Post-operative use of analgesics and antibiotic is measured using a telephone call at three to five days after the treatment.

Completion date
13/08/2017

Eligibility

Key inclusion criteria
1. Clinically diagnosed with symptomatic apical periodontitis but without systemic involvement, manifest as intra- or extra-oral swelling or fever
2. Spontaneous pain and/or pain on percussion and palpation
3. Necrotic (non-bleeding) pulp in canal orifice/s
4. Pain >4 on Numeric Rating Scale
5. Accepting a phone call within 3-5 days and a new appointment within 2 weeks
6. Aged 18 years of age and older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previous endodontic treatment
2. Intra- and/or extraoral swelling, fever
3. Currently on prescribed antibiotics

Date of first enrolment
01/03/2012

Date of final enrolment
30/05/2016

Locations

Countries of recruitment
Sweden

Study participating centre
Malmö University
Faculty of Odontology
Malmö
Sweden
205 06 Malmö, Sweden

Sponsor information

Organisation
Malmö University

ROR
https://ror.org/05wp7an13

Funder(s)

Funder type
University/education

Funder Name
Malmö Högskola

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Associate Professor Eva Wolf, Dept of Endodontics, Faculty of Odontology, Malmö University, 205 06 Malmö, Sweden. eva.wolf@mah.se

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes