ISRCTN84455971 https://doi.org/10.1186/ISRCTN84455971

Pulpotomy of carious teeth

Submission date
07/11/2017

Recruitment status
No longer recruiting

Registration date
09/11/2017

Overall study status
Completed

Last Edited
10/08/2018

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Dental caries (cavities) is the major threat to dental pulp (the centre part of the tooth) if left untreated, leading to tooth loss. The treatment of teeth with exposed cavities has been a controversial issue with two different points of view: a conservative approach with vital pulp therapy (pulpotomy) (a partial removal of the diseased pulp while keeping the tooth alive with a therapeutic dressing) and the more invasive but reliable approach with root canal therapy. A root canal therapy is a procedure that removes the infected pulp and then fills it with a rubber like material. Studies have found inflammation (swelling) to be confined to the area next to the carious exposure and not extending beyond 2 mm from the exposure site. So, in cases of carious exposure in vital teeth pulpotomy could be considered as an alternative treatment with success rates comparable to root canal treatment over 5 years follow-up using contemporary biologically active capping materials. The advantages of pulpotomy over a root canal include maintaining the sensation in the health pulp in the roots, and more conservative with lower cost. The aim of this clinical study is to assess the outcome of full pulpotomy in symptomatic permanent teeth with carious exposures using a biocompatible material (biodentine), in order to recommend as an alternative treatment method.

Who can participate?
Adults over the age of 18 who attend the post graduate clinics at Faculty of Dentistry at Jordan University of Science and Technology in Jordan.

What does the study involve?
The tooth is tested using cold test and x-rays of the tooth are taken to establish diagnosis. Participants are asked to record their pain score at attendance. The tooth is frozen using local anesthesia and isolated with dental dam as in routine root canal therapy. Partial pulp removal (pulpotomy) is done, a dressing material is placed, and the tooth is restored. Another x-ray is taken. The participant is contacted by phone after two days to score the pain levels. They are then called at six months, 12 months and yearly up to five years for examination of the tooth.

What are the possible benefits and risks of participating?
Participants may benefit from having caries being removed and the tooth will be treated using biocompatible material and will be restored for free. Viability of the pulp in the root will be

maintained and the tooth strength is preserved. There is a risk of pain to continue after 2 days, then routine root canal treatment will be performed for no charge. At subsequent follow up if there is signs of failure root canal treatment will be offered as well.

Where is the study run from?
The study is being run by Jordan University of Science and Technology, and takes place in the postgraduate endodontic clinics at the Faculty of Dentistry (Jordan)

When is the study starting and how long is it expected to run for?
September 2015 to October 2021

Who is funding the study?
Deanship of research, Jordan University of Science and Technology (JUST) (Jordan)

Who is the main contact?
A/Prof. Nessrin Taha
n.taha@just.edu.jo

Study website
NA

Contact information

Type(s)
Scientific

Contact name
Dr Nessrin Taha

ORCID ID
http://orcid.org/0000-0003-3233-8850

Contact details
P.O Box 3864
Irbid
Jordan
22110
+962 776 566110
n.taha@just.edu.jo

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
156/2016 resaerch grant nomber

Study information

Scientific Title
Outcome of Biodentine™ full pulpotomy in adult permanent teeth with carious exposures

Study objectives
Would Biodentine full pulpotomy be clinically and radiographically successful in symptomatic adult permanent teeth with carious exposure over 1-5 years follow up?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board Jordan University of science and technology and King Abdullah University Hospital, 21/04/2016, ref: 13/95/2016

Study design
Interventional non randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Deep caries, irreversible pulpitis, symptomatic apical periodontitis

Interventions
The following steps are included in this procedure:
1. The carious tooth will be anesthetized using local anesthesia.
2. Full pulpotomy will be performed for the tooth under rubber dam isolation.
3. Biodentine capping material will be placed
4. The tooth will be permanently restored with resin composite or amalgam.
5. Post operative periapical radiograph will be taken

The tooth is tested using cold test and periapical radiograph of the tooth are taken to establish diagnosis. Participants are asked to record their pain score at attendance. The tooth is anesthetized using local anesthesia and isolated with dental dam as in routine root canal therapy. Partial pulp removal (pulpotomy) are done, a dressing material are placed, and the

tooth is restored. A radiograph is taken. The participant is contacted by phone after two days to score the pain levels. They are then called at six months, 12 months and yearly up to five years for clinical and radiographic examination of the tooth.

Intervention Type
Other

Primary outcome measure
1. Clinical success is measured using percussion, palpation, inspection tests of the treated tooth at 6 months, 1 year, 3 years, 5 years post treatment
2. Radiographic success is measured by periapical radiograph at 6 months, 1 year, 3 years, 5 years post treatment

Secondary outcome measures
Resolution of symptoms are measured using Visual analogue scale and 0-10 scale at 2 days after treatment.

Overall study start date
18/09/2015

Completion date
01/10/2021

Eligibility

Key inclusion criteria
1. The patient should be ≥ 18 years old with non-contributory medical history, either male or female
2. Has a molar tooth with deep caries exposing the pulp or extending ≥ 2/3 into dentine and subsequent clinical pulp exposure
3. Tooth should be vital on cold testing, restorable and free from advanced periodontal disease
4. Clinical diagnosis of irreversible pulpitis with /without periapical rarefaction
5. Soft tissues around the tooth are normal with no swelling or sinus tract
6. Vital bleeding pulp tissue should be present in all canals after complete pulpotomy
7. Haemostatis should be achieved after complete pulpotomy within 6 minutes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Teeth with immature roots
2. Non restorable teeth
3. Negative response to cold testing, presence of sinus tract or swelling
4. No pulp exposure after caries excavation
5. Bleeding could not be controlled after partial pulpotomy in 6 minutes
6. Insufficient bleeding after pulp exposure, the pulp is judged necrotic or partially necrotic

Date of first enrolment
01/04/2016

Date of final enrolment
01/10/2016

Locations

Countries of recruitment
Jordan

Study participating centre
Jordan University of Science and Technology. Irbid Jordan
P.O box 22110
Jordan University of Science and Technology
Faculty of Dentistry
Irbid
Jordan
22110

Sponsor information

Organisation
Jordan University of Science and Technology

Sponsor details
Jordan University of Science and Technology
Institutional Review board
Irbid
Jordan
22110
+962 272 01000
irb@kauh.jo

Sponsor type
University/education

Website
www.just.edu.jo

ROR
https://ror.org/03y8mtb59

Funder(s)

Funder type
University/education

Funder Name
Jordan University of Science and Technology

Alternative Name(s)
, JUST

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Jordan

Results and Publications

Publication and dissemination plan
I am intending to publish the outcome of the study after 1 year, 3 years and 5 years follow up. The first publication will be submitted in November 2017.

Intention to publish date
01/11/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from A/Prof Nessrin Taha at n.taha@just.edu.jo.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No