ISRCTN17574766 https://doi.org/10.1186/ISRCTN17574766

Repairing experimental tooth root perforations with different commercial materials

Submission date
31/01/2017

Recruitment status
No longer recruiting

Registration date
02/02/2017

Overall study status
Completed

Last Edited
02/02/2017

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
A root canal is a dental procedure that treats infection inside the tooth and prevents bacteria from re-entering the tooth. A possible side effect of this treatment is a tooth perforation (hole) which means bacteria can enter the tooth as there is contact with tissue that surrounds and supports the teeth (periodontium) and the root system of the tooth. A perforation needs to be sealed as soon as possible in order to save the tooth. This is usually done with gutta-percha, which is a rubber-like material. However, other sealants can be used to see if they help repair the perforation, such as white MTA and Biodetine. These sealants are made from a calcium-silicate based material and may help periodontium tissue to repair itself. This study aims to investigate the response of periodontal tissue when white MTA and Biodentine are used to seal teeth over a three-month period.

Who can participate?
Adults needing a root canal and have two teeth that need to be pulled.

What does the study involve?
Participants undergo their scheduled root canal according to standard care. Participants are randomly allocated to one of two groups. Those in group one have one tooth repaired with MTA and one tooth repaired with according to the standard practice. Those in group two have one tooth repaired with Biodentine and one tooth repaired according to the standard practice. Three months after the treatment, teeth are pulled and implants are placed done to the standard level of care. Samples from the tooth are taken during the process and are analysed to see how well they did at repairing the tooth perforation and if the periodontal tissue repaired itself.

What are the possible benefits and risks of participating?
Participants may benefit from a discount on the treatment price. There is a possible risk that participants may experience mild pain after the treatment and it can delay their treatment process.

Where is the study run from?
Clinica Odontoiatrica Salzano & Tirone (Italy)

When is the study starting and how long is it expected to run for?
October 2014 to May 2016

Who is funding the study?
Clinica Odontoiatrica Salzano & Tirone (Italy)

Who is the main contact?
Dr Tirone Federico
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Response of periodontium to MTA and Biodentine: a randomised controlled histological study on humans

Study objectives
This study is aimed at investigating the response of periodontal tissues in contact with white MTA and Biodentine over a three-month period, in order to determine whether periodontal regeneration in contact with such materials is possible in humans.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Cuneo's Hospital, 17/12/2014, ref: 07/14

Study design
Single-centre single-blind randomised controlled histological study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Root perforation

Interventions
Participants are randomly assigned to one of two groups, either the MTA group of the Biodentine group. Two teeth that are scheduled for extraction are randomly assigned to either being designated the test tooth or the control tooth. Randomisation of treatment groups is generated from a computer program, in order to choose the treatment with either MTA or Biodentine. Only one investigator is aware of the sequence and is allowed to access the file. The randomised codes are put into sequentially sealed envelopes which are opened by the investigator performing the endodontic treatment after preparing the perforation, so as to determine the treatment assigned to each tooth. In order to establish whether the test tooth had to be the right or the left one, a further couple of envelopes containing the words "test" and "control" was prepared for each patient and then the envelopes were sealed. At this point, an independent assistant is asked to write "right" and "left" on the envelopes. Participants undergo a root canal (endodontic treatment) under local anesthesia. The root canals are done according to the standard care of practice until the perforation part of the procedure. At this point of the procedure, the envelopes are opened and the perforation was done according to the randomization process.

Group 1 (MTA): The test tooth perforation is repaired with MTA and control tooth perforation is filled with root canal sealer and gutta-percha during the endodontic treatment.

Group 2 (Biodentine): The test tooth perforation is repaired with Biodentine and control tooth perforation is filled with root canal sealer and gutta-percha during the endodontic treatment.

Three months after the root canal, the teeth are extracted and implants are placed. This is done according to the standard care of practice. Biopsy samples are taken from the tooth during the extraction process and stored in a glycolmethacrylate resin. These are then analysed under a microscope in a laboratory.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Formation of mineralised tissue over the filling material material is measured using the histological analysis at 3 months
2. PDL fibres orientation is evaluated using thehistological analysis under polarised light at 3 months
3. Presence of inflammatory cell infiltrate, classified as follows: null, when there are no inflammatory cells; mild, when there are few inflammatory cells; moderate, when inflammatory cells do not replace the normal tissue; severe, when inflammatory cells replace the normal tissue is measured using the histological analysis at 3 months

Secondary outcome measures
1. The presence or absence of a fibrous capsule formation is measured using histological analysis at 3 months
2. Root resorption is measured using histological analysis at 3 months
3. Ankylosis is measured using histological analysis at 3 months
4. Epithelial proliferation is measured using histological analysis at 3 months

Overall study start date
01/10/2014

Completion date
31/05/2016

Eligibility

Key inclusion criteria
1. Adults aged 18-60 years old
2. Healthy patients
3. Needing all-on-4 rehabilitation
4. Having at least two vital and periodontally healthy monoradicular teeth scheduled for extraction

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit

60 Years

Sex
Both

Target number of participants
6

Key exclusion criteria
1. Clinically significant medical history
2. Treated with immunosuppressive therapy or immunocompromised
3. Undergoing radiotherapy in the head/neck area
4. Previously treated or under treatment with intravenous amino-bisphosphonates
5. Pregnant or breastfeeding
6. Refusing to be included in the research protocol

Date of first enrolment
18/12/2014

Date of final enrolment
02/01/2016

Locations

Countries of recruitment
Italy

Study participating centre
Clinica Odontoiatrica Salzano Tirone
Via Cascina Colombaro 37c
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Sponsor information

Organisation
Clinica Odontoiatrica Salzano Tirone

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01cbq7w74

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Clinica Odontoiatrica Salzano Tirone

Results and Publications

Publication and dissemination plan
Planning publication in a high impact journal.

Intention to publish date
30/01/2017

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. Tirone Federico, federico.tirone@gmail.com

IPD sharing plan summary
Available on request