

Mineral trioxide aggregate (MTA) as an alternative root canal filling material

Submission date 08/06/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/08/2016	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Periapical periodontitis is a lesion around the top (apex) of a tooth root caused by bacterial invasion of the pulp of the tooth. The primary goal of root canal obturation is to prevent the spread of bacteria and bacterial toxins from the canals into the periapical tissues. Any residual bacteria not eliminated during root canal instrumentation should be sealed by the obturation material and rendered harmless by nutrient deprivation. Gutta percha cones are standard core obturation materials that are compacted into the prepared root canal system using lateral or vertical compaction. However they do not adhere to the dentin surface, thus leaving a gap. Therefore, root canal sealers must be used to seal the space between the gutta percha cones and dentinal walls.

Mineral Trioxide Aggregate (MTA) cement without gutta percha cones has been demonstrated as a successful root canal filling material in immature (young) teeth. The aim of this study is to compare MTA cement with conventional root canal filling (gutta-percha cones and root canal sealers) in mature (adult) teeth.

Who can participate?

Healthy female volunteers requiring root canal treatment

What does the study involve?

Participants will be randomly allocated to one of two groups: control or intervention.

Control group: gutta-percha cones and root canal sealer (AH plus) will be used in warm vertical technique to create 4 mm apical plug after complete cleaning and shaping. The remaining root canal space will be either filled with thermo-plasticized gutta-percha or left for post cementation, depending on the remaining tooth structure.

Treatment group: MTA cement (ProRoot MTA) will be used to create 4 mm apical plug after complete cleaning and shaping. The remaining root canal space will be either filled with thermo-plasticized gutta-percha or left for post cementation, depending on the remaining tooth structure.

What are the possible benefits and risks of participating?

Participants will receive root canal treatment and referral for final coronal restoration, follow up visits for 5 years. The treatment and follow up are free of charge.

Where is the study run from?
College of Dentistry, King Saud University (KSU) and under the care of College of Dentistry
Research Center. Saudi Arabia.

When is the study starting and how long is it expected to run for?
February 2010 to June 2024.

Who is funding the study?
King Saud University (KSU)

Who is the main contact?
Reem Alsulaimani
reem@ksu.edu.sa

Contact information

Type(s)
Scientific

Contact name
Dr Reem Alsulaimani

ORCID ID
<http://orcid.org/0000-0002-3275-3598>

Contact details
King Saud University
College of Dentistry
Department of Restorative Dental Science
Riyadh
Saudi Arabia
11545
+966114677420
reem@ksu.edu.sa

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CDRC FR0235

Study information

Scientific Title

Evaluation of periapical healing following apical filling with mineral trioxide aggregate in mature teeth: a randomized controlled trial

Acronym

MTAO - Mineral Trioxide Aggregate Obturation

Study objectives

H0: Periapical healing is not significantly affected by MTA obturation when compared to conventional gutta-percha cones and root canal sealers.

H1: Periapical healing is significantly affected by MTA obturation when compared to conventional gutta-percha cones and root canal sealers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board and Ethical Approval Committee at the College of Dentistry, King Saud University, 18/05/2015, ref 353621 (FR 0235).

Study design

Interventional single-centre study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Root canal therapy is indicated when the pulp chamber of a tooth is contaminated by bacteria causing the canals to become infected and development of periapical pathosis. The procedure is accomplished under local anesthesia and rubber dam isolation by creating a small opening in the biting surface of the tooth that will allow it to be disinfected and then sealed with either Gutta percha or Mineral trioxide aggregate (MTA) cement. Gutta percha is a gold standard obturation material whereas MTA demonstrated as successful root end filling material and more recently used as obturation material. The sealing of the canals prevents subsequent passage of bacteria into or out of the tooth.

Health condition(s) or problem(s) studied

Patient requires root canal treatment for teeth with apical periodontitis.

Interventions

Control group: conventional root canal filling with gutta-percha cones and root canal sealer.

Treatment group: Mineral Trioxide Aggregate cement

Intervention Type

Procedure/Surgery

Primary outcome measure

Periapical healing assessed by conventional periapical radiographs.
Measured 5 times, every 12 month post-operative for 5 years.

Secondary outcome measures

Periapical healing assessed by cone beam computed tomography.
Measured twice, 1st and 5th year only.

Overall study start date

05/02/2010

Completion date

01/06/2024

Eligibility**Key inclusion criteria**

Included patients will be adult, healthy females who agreed to participate in the study and signed a consent form. The study will include mature teeth with radiographic periapical pathosis greater than 5mm in diameter.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

100

Key exclusion criteria

The study sample will exclude teeth that are not restorable, teeth diagnosed with chronic periodontitis with advanced loss of periodontal support, third molars, and teeth with open apex.

Date of first enrolment

07/03/2010

Date of final enrolment

26/06/2018

Locations**Countries of recruitment**

Saudi Arabia

Study participating centre

King Saud University

King Abdullah Road

P.O. Box 60169

Riyadh

Saudi Arabia

11545

Sponsor information

Organisation

King Saud University

Sponsor details

King Abdulla Road.

P. O. Box 60169

Riyadh

Saudi Arabia

11545

Sponsor type

University/education

ROR

<https://ror.org/02f81g417>

Funder(s)

Funder type

University/education

Funder Name

King Saud University

Alternative Name(s)

, KSU

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Saudi Arabia

Results and Publications

Publication and dissemination plan

The results of MTA application in non-surgical setting is complete and at the stage of manuscript writing.

The results of the completed study will be available after completion of 5 years recall.

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/08/2016		Yes	No