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Using olive oil in the removal of broken tools from the root canal

Submission date
03/11/2022

Recruitment status
No longer recruiting

Registration date
04/11/2022

Overall study status
Completed

Last Edited
14/11/2022

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
Root canal treatment is a dental procedure used to treat infection at the centre of a tooth. Broken instruments within the root canal during root canal treatment are an unwanted and frustrating complication. This study aims to evaluate the effectiveness of using olive oil as a lubricant while removing broken instruments from root canals and the time required compared with using ethylenediaminetetraacetic acid (EDTA) as a lubricant.

Who can participate?
Patients aged between 21 and 54 years with broken instruments in the root canal of the molar tooth.

What does the study involve?
Participants are randomly allocated to one of two groups. The study involves removing the broken instruments using olive oil as the lubricant during the procedure for the study group, and EDTA as the lubricant for the control group.

What are the possible benefits and risks of participating?
The benefits are the removal of the SI and filling of the root canal. There are no risks as in the worst cases the tool will not be removed, which will lead to different treatment options.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
November 2020 to November 2022

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Ahmad Alaloul, ahmad.alaloul@damascusuniversity.edu.sy

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
ID # 417, dated 16/11/2020

Study information

Scientific Title
Comparison between EDTA and olive oil as lubricant agents in intracanal separated instruments removal for lower molars: in vivo study

Study objectives
Null hypothesis: olive oil is not effective compared to ethylenediaminetetraacetic acid (EDTA) as a lubricant agent in endodontic treatment
Alternative hypothesis: olive oil is effective compared to EDTA as a lubricant agent in endodontic treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/11/2020, the Institutional Review Board (IRB) at Damascus University (postal address: not available; +963 (0)1133923482; srd@damasuniv.edu.sy), ref: 417

Study design
Two-arm randomized parallel superiority trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Separated instrument (SI) in the middle third of the mesio-lingual canal of mandibular first molars

Interventions
Current interventions as of 14/11/2022:

Participants are randomized with a 1:1 allocation ratio (simple randomizations using Excel sheets) to use either EDTA (15 molars) or olive oil (15 molars) as the lubricant agent used in SI removal in curved canals.

An additional 30 teeth are used as a control to test the effectiveness of EDTA and olive oil in straight canals and they were divided into 2 groups as well (15 teeth olive oil, 15 teeth EDTA).

A cone beam computed tomography (CBCT) image is taken to study the case. Under local anaesthesia and rubber dam isolation, all caries and previous restorations are removed. The access cavity is refined using an Endo-Z bur. The working length in canals without SI is determined with an apex locator. Mesio-buccal and distal orifice canals are closed using cotton balls. Terauchi's technique is followed in SI retrieval. A micro-trephine bur is used to expose the coronal third of the instrument. After filling the canal with the lubricant agent until the middle of the pulp chamber, the ultrasonic tip is activated at the medium power settings by push and pull movement in the cavity as far away as possible from the SI until it is removed.

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Previous interventions:

Participants are randomized with a 1:1 allocation ratio (simple randomizations using Excel sheets) to use either EDTA (15 molars) or olive oil (15 molars) as the lubricant agent used in SI removal.

A cone beam computed tomography (CBCT) image is taken to study the case. Under local anaesthesia and rubber dam isolation, all caries and previous restorations are removed. The access cavity is refined using an Endo-Z bur. The working length in canals without SI is determined with an apex locator. Mesio-buccal and distal orifice canals are closed using cotton balls. Terauchi's technique is followed in SI retrieval. A micro-trephine bur is used to expose the coronal third of the instrument. After filling the canal with the lubricant agent until the middle of the pulp chamber, the ultrasonic tip is activated at the medium power settings by push and pull movement in the cavity as far away as possible from the SI until it is removed.

Intervention Type
Procedure/Surgery

Primary outcome(s)

Successful removal of SI (0= not successful, 1= successful), measured at the time of treatment, the same day as the operation

Key secondary outcome(s))
Time until the removal of the SI measured in minutes at the time of the operation

Completion date
01/11/2022

Eligibility

Key inclusion criteria
1. Patients aged between 21 and 54 years
2. SI in the middle third of the mesio-lingual canal of mandibular first molars
3. Attend the endodontic department during the study period
4. Agreed to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Systemic diseases that compromise general immune status
2. Unrestorable teeth
3. Curved mesio-lingual canal (>30 degrees)
4. Long mesio-lingual canal (>25 mm)
5. >5 mm SI length

Date of first enrolment
01/05/2021

Date of final enrolment
01/05/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty of Dental Medicine
Department of Endodontics
Almazzah St
Damascus
Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

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 the main author Dr Ahmad Alaloul (ahmad.alaloul@damascusuniversity.edu.sy)

IPD sharing plan summary

Available on request