

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

Submission date 03/11/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/11/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/11/2022	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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.

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 measure

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

Secondary outcome measures

Time until the removal of the SI measured in minutes at the time of the operation

Overall study start date

16/11/2020

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

Age group

Adult

Sex

Both

Target number of participants

60 (30 for the curved canals, and 30 for control in straight canals)

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**

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Sponsor information

Organisation

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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

Publication and dissemination plan

The authors are preparing the first manuscript for publication and will publish it in a Q1 journal as soon as the manuscript is ready

Intention to publish date

15/11/2022

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