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Effectiveness of orthodontic mini-implant covers

Submission date
04/05/2020

Recruitment status
No longer recruiting

Registration date
06/05/2020

Overall study status
Completed

Last Edited
06/05/2020

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
Orthodontic mini-implants are very small (1.5 – 2 mm wide) customised titanium alloy screws which acts as an anchor point in the jaw. Mini-implants are frequently placed between the roots of teeth, but may also be sited in the roof of the mouth. They are then connected to a fixed brace to help move the teeth.
Orthodontic Mini implants is a procedure which is currently popular and commonly used to reinforce anchorage need in an orthodontic treatment. Despite it resulting in absolute anchorage, there are issues (of varying percentages) related to its usage such as pain due to insertion and impingement of the MI head to the buccal mucosa and ulceration, implantitis and failure of the MI to name a few.
Thus the aim of this study is to look further into this matter by means of RCT. The main aim of this study is to evaluate the pain score of patients who are treated with different methods.

Who can participate?
Adult orthodontic patients aged 18 - 30 years, requiring MI placement as part of anchorage reinforcement of their orthodontic treatment, and in good health.

What does the study involve?
Participants will be randomly allocated to receive orthodontic mini implants using three different methods and will be followed up for 30 days.

What are the possible benefits and risks of participating?
The use of the MI covers have shown to help reduce the pain levels in the subjects. The MI covers can be used as a method to help reduce pain and discomfort for patients, by protecting the tongue, cheek and lips from mucosal injury and trauma which could lead to ulceration.
Risks: none

Where is the study run from?
University Teknologi MARA (UiTM), Jalan Hospital Postgraduate Orthodontic Clinic (Malaysia)

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

Who is funding the study?
Universiti Teknologi MARA (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
600-IRMI 5/1/6

Study information

Scientific Title
Clinical assessment of orthodontic mini-implant covers and their effect on oral health quality of life: a randomised controlled trial

Study objectives
1. There will be a difference in the pain level and discomfort in all the three groups (Control, Soft Flow and Composite resin)
2. There will be a difference in the occurrence of ulceration in all the three groups (Control, Soft

Flow and Composite resin)
3. There will be a difference between the subject's Oral health-related quality of life (OHRQoL) in all the three groups with or without the MI covers (Control, Soft Flow and Composite resin)
4. There will be a difference in the cost-effectiveness between the mini implant covers used (Soft Flow and Composite resin groups)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/11/2017, The Research and Ethics Committee of UiTM (Universiti Teknologi MARA, Aras 3, Bangunan Wawasan, 40450 Shah Alam, Selangor, Malaysia; +603-55442094; irmiuitm@salam.uitm.edu.my), ref: REC/294/17

Study design
Prospective single centred randomised clinical trial with three-arm parallel groups of a prospective 1:1:1 allocation ratio

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Oral health (orthodontic)

Interventions
The patients will be allocated randomly by stratified block randomisation. Recruited patients will be active orthodontic patients that require orthodontic mini implants (MIs) as part of their orthodontic treatment plan.
Three groups involved will be:
1. Control group
2. Soft flow group (SF)
3. Composite resin (CR) group

Only the SF and CR groups receive interventions in which the Soft flow material or the Composite resin material will be placed on the MI head after the MI insertion. The parameters observed will be the Pain score, oral health impact profile and cost-effectiveness of the MI covers as well as the MI failure. The nine different time points are: B0 (baseline- before MI insertion for Control group) and T0 (immediately after MI insertion fr SF and CR groups); T1 (1 hour after MI insertion); T12 (12 Hours after MI insertion); T24 (24 hours after MI insertion); TD2 (2 days after MI insertion); TD3 (3 days after MI insertion); TD7 (7 days after MI insertion); TD14 (14days after MI insertion) and TD30 (30 days after MI insertion).

Intervention Type
Other

Primary outcome(s)
Pain score (Numeric Rating Scale) at T0-TD30 at B0 (baseline- before MI insertion for Control group) and T0 (immediately after MI insertion fr SF and CR groups); T1 (1 hour after MI

insertion); T12 (12 Hours after MI insertion); T24 (24 hours after MI insertion); TD2 (2 days after MI insertion); TD3 (3 days after MI insertion); TD7 (7 days after MI insertion); TD14 (14days after MI insertion) and TD30 (30 days after MI insertion)

Key secondary outcome(s))
1. Oral health-related quality of life using the Modified Short Oral Health Impact profile -14 (at T0 and TD30)
2. Cost-Effectiveness of the MI covers calculated by comparing the current the cost of each material (per syringe) and the amount of MI covers that are produced by a single syringe

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. Orthodontic patients requiring MI placement as part of anchorage reinforcement of their orthodontic treatment
2. Age 18 years up to 30 years old
3. Healthy patients with no underlying systemic diseases or illness
4. Requiring posteriorly and buccally placed MI on the maxilla or mandible (distal to the canines)
5. Healthy periodontium and good oral hygiene

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
39

Key exclusion criteria
1. Pre-existing oral soft tissue conditions (such as Recurrent Apthous Stomatitis)
2. Previously failed MI or reinsertion of MI
3. On medications that may alter the oral health status
4. Underlying medical conditions such as diabetes
5. Cleft lip and palate patients
6. Smokers
7. Allergies to metals such as stainless steel or titanium

Date of first enrolment
10/11/2017

Date of final enrolment
30/04/2019

Locations

Countries of recruitment
Malaysia

Study participating centre
University Teknologi MARA (UiTM)
Postgraduate Orthodontic Clinic
Faculty of Dentistry
Jalan Hospital
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Sponsor information

Organisation
Universiti Teknologi MARA

ROR
https://ror.org/05n8tts92

Funder(s)

Funder type
University/education

Funder Name
Universiti Teknologi MARA

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date