

Effectiveness of orthodontic mini-implant covers

Submission date 04/05/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/05/2020	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

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

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 measure

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)

Secondary outcome measures

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

Overall study start date

06/12/2016

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

39 participants. 13 in each group.

Total final enrolment

39

Key exclusion criteria

1. Pre-existing oral soft tissue conditions (such as Recurrent Aphthous 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

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Sponsor information**Organisation**

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Funder(s)

Funder type
University/education

Funder Name
Universiti Teknologi MARA

Results and Publications

Publication and dissemination plan

The publication plan is to divide the trial in 2 parts (two publications). The first part is to report the primary findings on the pain scores and the occurrence of ulceration as well as the dislodgement of the MI covers and cost effectiveness. The second part is to report on the secondary findings which is the oral health impact profile.

Intention to publish date
10/05/2020

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