

Conventional implants vs mini implants used to retain full lower dentures

Submission date 05/07/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/07/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/02/2017	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

There are 3.7 million people in Britain who have no natural teeth and most are over 65. Many of these individuals have difficulty wearing lower dentures, which causes difficulties in chewing and speaking resulting in a significant impact on quality of life, so much so that the World Health Organisation classifies these individuals as having a disability. Titanium implants screwed into the jaw hold lower dentures in place. Mini-implants have recently been developed. They are smaller and cheaper than traditional implants and are less painful to place. However, the long-term costs and benefits of mini-implants have not been compared with traditional implants. We will therefore undertake an initial study to compare mini-implants with traditional implants.

Who can participate?

Patients lacking teeth, who are referred to Manchester University Dental Hospital and meet the eligibility criteria will be able to take part.

What does the study involve?

After some initial tests patients will be randomly assigned to receive either mini or traditional implants. An appointment will be made for these to be fitted and the patients will also attend 1 week, 2 months & 6 months after surgery in order to make further assessments. Patients will need to complete a chewing test and questionnaires at these visits. Patients who receive the mini implants may find the surgery less painful but it is possible the implants may not be as long lasting. After the study the outcomes in the 2 groups will be analysed. The initial study will also tell us how quickly we can recruit patients and how many will stay once they have been recruited. The study will also help us build a team and give information on how to effectively manage a large-scale study.

What are the possible benefits and risks of participating?

Placing both types of implants requires a minor operation. The operation for the traditional implant is more extensive and may produce more pain and swelling. Any surgical procedure has risks of bleeding and infection. There is also a small risk of nerve damage or jaw fracture. Once it has been decided which implant you will receive the surgical team will discuss the procedure and potential side effects with you in greater detail. If you receive the mini implants you may find the operation easier to undergo but as the implants are smaller there is a chance that they might not

be as long-lasting. Participating in the study does not require you to attend any additional appointments but appointments may take a little longer as we need to measure how well you can chew and you will need to complete several questionnaires. In total it may take 20 to 30 minutes to complete questionnaires at each visit, plus a few minutes for the chewing test. If you don't want to spend the extra time doing these tests you do not have to take part in the study.

Where is the study run from?

Manchester University Dental Hospital (UDHM) (UK)

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

Patient recruitment is planned to start in September 2013 and will take place over one year.

Who is funding the study?

The study is funded by the National Institute of Health Research (NIHR), UK (Research for Patient Benefit funding stream), with the supply of mini implants funded by the manufacturer (3M).

Who is the main contact?

Helen Flight

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

14653

Study information

Scientific Title

A pilot randomised controlled trial of Conventional Implants vs Mini Implants used to retain full lower DENTures

Acronym

CIMI DENT

Study objectives

Titanium implants screwed into the jaw hold lower dentures in place, but implants are costly and require surgery that some patients may not cope with. Mini-implants have recently been developed; they are smaller and cheaper than conventional implants and are much less traumatic to place. However, the long-term costs and benefits of mini-implants have not been compared with conventional implants in high quality clinical trials. This pilot trial will gather the necessary information to inform a future large scale trial of conventional versus mini implants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

13/NW/0384

Study design

Randomised; Interventional; Design type: Not specified, Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Oral & Dental

Interventions

1. Conventional dental implant (Astra)
2. Mini Dental Implant (3M)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Inform a large randomised trial of conventional vs mini implants; Timepoint(s): Throughout conduct of the pilot trial, each patient is followed-up for 6 months post surgery.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/2013

Completion date

30/11/2014

Eligibility**Key inclusion criteria**

1. Patient has been edentulous (no teeth at all) for at least 12 months
2. Bone height = 10mm in the interforamina region (anterior section of the mandible), therefore suitable for implant placement without bone grafting
3. Cawood and Howell Classification V and VI (severely resorbed mandible)
4. New lower denture remains unsatisfactory
5. Able to give informed consent to participate in the study
6. Aged 18 or over

Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 44; UK Sample Size: 44

Key exclusion criteria

1. Radiographic confirmation that the patient has insufficient mandibular bone for either procedure
2. Significant medical history contraindicating the placement of either conventional or miniimplants (e.g. bisphosphonate treatment, radiotherapy treatment, poorly controlled diabetes, longterm steroid use)
3. Current smoker, or have smoked in last six months

4. Unable to maintain adequate level of oral hygiene
5. Requires sedation for dental treatment
6. Previous failed implant treatment
7. Allergic to or unable to tolerate any of the ingredients of gummy jelly (an outcome measure)

Date of first enrolment

01/11/2013

Date of final enrolment

30/11/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

550 Wilmslow Road

Manchester

United Kingdom

M20 4BX

Sponsor information

Organisation

Central Manchester University Hospitals NHS Trust (CMFT) (UK)

Sponsor details

Genetic Medicine

Manchester Royal Infirmary

Oxford Road

Manchester

England

United Kingdom

M13 9WL

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00he80998>

Funder(s)

Funder type

Government

Funder Name

NIHR Research for Patient Benefit (RfPB) (UK) Grant Codes: PB-PG-0212-27050

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/02/2017		Yes	No
HRA research summary			28/06/2023	No	No