ISRCTN87342238 https://doi.org/10.1186/ISRCTN87342238

Conventional implants vs mini implants used to retain full lower dentures

Submission date 05/07/2013	**Recruitment status** No longer recruiting
Registration date 05/07/2013	**Overall study status** Completed
Last Edited 17/02/2017	**Condition category** Oral Health

✓ Prospectively registered
? Protocol not yet added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
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 dont 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
helen.flight@christie.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Helen Flight

Contact details
550 Wilmslow Road
Manchester
United Kingdom
M20 4BX
+44 (0)161 446 3000
helen.flight@christie.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
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 hypothesis
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

Condition
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

Overall study end date
30/11/2014

Eligibility

Participant 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

Participant 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 steriod 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)

Recruitment start date
01/11/2013

Recruitment end date
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