ISRCTN65954262 https://doi.org/10.1186/ISRCTN65954262

Randomized controlled clinical trial of impression techniques designed to alleviate the pain of lower dentures in patients with severely resorbed mandibles

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
04/09/2012

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436189315

Study information

Scientific Title

Study objectives
1. To provide 3 lower dentures for each research participant each one identical except for the manner in which the fitting surface has been contoured
2. To allow the research participant to assess each denture
3. To allow the research participant to choose the denture they find the most comfortable

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Oral Health: Resorbed mandibles

Interventions
Comparison of impression techniques

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

To determine which impression procedure produces the most comfortable lower denture

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2006

Completion date
01/03/2009

Eligibility

Key inclusion criteria
1. Patients able to attend
2. Edentulous in the lower arch with the mental foramen apparent clinically or radiographically on the denture bearing area of the lower residual alveolar ridge

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2006

Date of final enrolment
01/03/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Leeds Dental Institute
Leeds
United Kingdom
LS2 9LU

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Industry

Funder Name
Johnson & Johnson Wound Management (UK)

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	01/11/2010		Yes	No