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	 Prospectively registered Protocol
Registration date 28/09/2007	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 04/09/2012	Condition category Oral Health	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

 Patients able to attend
 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