

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 ☒ 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

Contact name
Mr AJ Blance

Contact details
Leeds Dental Institute
University of Leeds
Leeds
United Kingdom
LS2 9LU
+44
a.j.blance@leeds.ac.uk

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Oral Health: Resorbed mandibles

Interventions

Comparison of impression techniques

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

To determine which impression procedure produces the most comfortable lower denture

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

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

Funder(s)

Funder type

Industry

Funder Name

Johnson & Johnson Wound Management (UK)

Results and Publications

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