

A pilot study to examine factors associated with excessive gagging in denture patients. A randomised controlled trial

Submission date 30/09/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/10/2011	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

N0013146125

Study information

Scientific Title

Study objectives

That there is no difference between the success of and impact on oral health of patients of lower cobalt chromium distal extension saddle partial dentures and single cantilever distal extension resin bonded bridges.

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

Interventions

Patients suitable for cobalt chromium lower distal extension saddle partial dentures made at Guy's Hospital will be randomised into two groups:

1. One group will have the dentures
 2. The other will have one or two distal cantilever minimum preparation resin bonded bridges
- The success, ongoing problems, maintenance requirements and impact on oral health of the different restorations will be monitored over 5 years.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Fit of dentures
2. Need for adjustment,
3. Acceptability
4. Patient wear of dentures

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2004

Completion date

30/09/2007

Reason abandoned (if study stopped)

Lack of funding

Eligibility**Key inclusion criteria**

100 patients attending Guy's Hospital for prostheses for edentulous distal extension saddle areas.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/03/2004

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Dental Prosthetics**

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

Department of Health

Sponsor details

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SW1A 2NL

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Guy's and St. Thomas' NHS Foundation Trust (UK)

Funder Name

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