

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	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 20/10/2011	Condition category Oral Health	☐ Individual participant data ☐ 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/03/2004

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Dental Prosthetics

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

Department of Health

Funder(s)**Funder type**

Government

Funder Name

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

Funder Name

Own account - NHS R&D Support Funding

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration