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

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

Primary study design
Interventional

Study design
Randomised controlled trial

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