

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

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/10/2011	<b>Condition category</b> 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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**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