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A balanced randomised controlled trial to examine the usefulness of alginate and polyvinylsiloxane as impression materials for cobalt chromium partial dentures.

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 12/04/2011	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0013146124

Study information

Scientific Title

Study objectives
That there is no difference between the fit of cobalt chromium partial dentures made using irreversible hydrocolloid impressions and those made using polyvinylsiloxane impressions.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Oral Health

Interventions
This is a randomised controlled trial, patients having cobalt chromium bonded saddle partial dentures made at Guy's Hospital will be randomised into two groups, comparing master impressions for partial dentures made using either irreversible hydrocolloid or polyvinylsiloxane impression material. Fit of the resulting cobalt chromium castings will be judged using an accepted method on master models and in the mouth, before and after adjustment. The amount of adjustment, if any, will be noted. Numbers of acceptable and unacceptable castings will be recorded.

Added July 2008: the trial was stopped due to lack of funding.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
alginate and polyvinylsiloxane

Primary outcome measure
Fit of denture castings, need for adjustment and acceptability.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2004

Completion date
31/08/2005

Reason abandoned (if study stopped)
Lack of funding

Eligibility

Key inclusion criteria
100 patients attending Guy's Hospital for bounded saddle partial dentures.

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
01/09/2004

Date of final enrolment
31/08/2005

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
Richmond House
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SW1A 2NL
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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
Own account

Funder Name
NHS R&D Support Funding

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