

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

Contact name

Dr Michael Fenlon

Contact details

Dental Prosthetics
Room 304, 25th Floor, Guy's Tower
Guy's Hospital
St Thomas' Street
London
United Kingdom
SE1 9RT
+44 (0)20 7188 7479
michael.fenlon@kcl.ac.uk

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Fit of denture castings, need for adjustment and acceptability.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2004

Date of final enrolment

31/08/2005

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

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration