

A balanced randomised controlled trial to examine the effect of using the altered cast technique on patient satisfaction with and fit of new distal extension saddle partial dentures

Submission date 30/09/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/04/2011	Condition category 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

N0013146122

Study information

Scientific Title

Study objectives

That there is no difference between the success of lower cobalt chromium distal extension saddle partial dentures made using or not using the altered cast technique.

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

Patients having lower cobalt chromium distal extension saddle partial dentures made at Guy's Hospital will be randomised into two groups. One group will have altered cast impressions made at the appropriate stage, the other group will not. Fit of the resulting dentures will be judged in the mouth using an accepted method. The amount of adjustment, if any, will be noted. Numbers of acceptable and unacceptable dentures will be recorded. Three months after the dentures are fitted patients will be sent a self-administered questionnaire to be completed to determine usage of the dentures.

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

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Fit of dentures, need for adjustment, acceptability, and patient wear of dentures.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2004

Completion date

31/10/2005

Reason abandoned (if study stopped)

Lack of funding

Eligibility**Key inclusion criteria**

Patients attending Guy's Hospital for cobalt chromium distal extension saddle partial dentures.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/03/2004

Date of final enrolment

31/10/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Dental Prosthetics

London

United Kingdom

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Sponsor information

Organisation

Department of Health

Sponsor details

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United Kingdom

SW1A 2NL

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dhmail@doh.gsi.org.uk

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

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