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 | 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

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 SE1 9RT

Sponsor information

Organisation Department of Health

Sponsor details Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 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

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