

Palatal implants versus headgear for orthodontic anchorage - a randomised controlled trial

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/07/2008	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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

Study information

Scientific Title

Study objectives

To evaluate the clinical effectiveness of the mid-sagittal implant as a method of preventing unwanted tooth movement (anchorage) during orthodontic treatment. The anchorage offered by implants will be compared with that from conventional orthodontic anchorage reinforcement techniques.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added July 2008: Ethical approval for this study was obtained from North Derbyshire Health and South Sheffield Local Research Ethics committees.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Oral Health: Orthodontics

Interventions

The anchorage offered by implants will be compared with that from conventional orthodontic anchorage reinforcement techniques.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Tooth movement. The difference in the mesial drift of the buccal teeth to be calculated:

- a. Relative to the cranial base using the Pitchfork analysis (Luecke and Johnston, 1992; Johnston, 1996) on the start and finish lateral cephalometric radiograph
- b. Relative to the palatal rugae, from the start and finish study models (Hoggan and Sadowsky, 2001)

Secondary outcome measures

1. Implant stability, discomfort and any signs of inflammation of the peri-implant tissues will be recorded with percussion tests using a Resonance Frequency Analyser (Meredith, 1998) and standard periodontal indices
2. Patient acceptability, compliance and discomfort measured using a questionnaire
3. Treatment outcome measured with the Peer Assessment Rating (PAR) index on the pre- and post-treatment study models

Overall study start date

01/01/2002

Completion date

01/06/2005

Eligibility

Key inclusion criteria

Added July 2008:

The patients in the study all needed absolute anchorage, and no forward movement of upper molars could be allowed for successful treatment.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

40 patients

Key exclusion criteria

Added July 2008:

Poor oral hygiene, unwilling to wear fixed appliances, unwilling to wear headgear or have the implant placed, and medical history precluding fixed appliance treatment.

Date of first enrolment

01/01/2002

Date of final enrolment

01/06/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Sheffield

Sheffield

United Kingdom

S10 2SZ

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Sheffield Teaching Hospitals (Central Campus) - UK

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results on main outcome	01/11/2007		Yes	No
Results article	results on other outcomes	01/01/2008		Yes	No