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

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 02/07/2008	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0059108300

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

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S10 2SZ

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Sheffield Teaching Hospitals (Central Campus) - UK

Results and Publications

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