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Is preliminary orthodontic treatment of benefit to the success of alveolar bone grafting?

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 29/01/2015	**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
N0265073460

Study information

Scientific Title
Is preliminary orthodontic treatment of benefit to the success of alveolar bone grafting?

Study objectives
A randomly controlled trial be established to test the following null hypothesis, that there is no difference in the outcome of the bone grafting procedure for patients who have had

orthodontic upper arch dental expansion treatment, prior to bone grafting, versus those who have not. In addition it is proposed to estimate the cost of treatment in terms of number of appointments.

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oral health

Interventions
Patients will be divided into two groups. 50 patients for each group. A control group will exist which will have bone grafting but with no preliminary orthodontic treatment, and a treatment group that has bone grafting preceded by orthodontic treatment to expand the upper dental arch. It is estimated that it will take 24 months to recruit this number of patients and a further year to collect the results. The investigations used are those usually obtained to assess growth and dental development in this group of patients.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
18/04/2008

Eligibility

Key inclusion criteria
Not provided at time of registration

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
18/04/2000

Date of final enrolment
18/04/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

University Hospital Birmingham NHS Trust (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes