

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

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/01/2015	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

Contact name
Mr MJC Wake

Contact details
Craniofacial
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

18/04/2000

Completion date

18/04/2008

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

100

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

England

United Kingdom

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

Sponsor details

The Department of Health
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

Hospital/treatment centre

Funder Name

University Hospital Birmingham NHS Trust (UK)

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