

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
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 29/01/2015	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

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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