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A prospective randomised clinical trial to assess change in nasal soft tissue dimensions in orthognathic surgery evaluated using a 3D imaging system

Submission date
28/09/2007

Registration date
28/09/2007

Last Edited
01/05/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
N0205182186

Study information

Scientific Title

Study objectives
To ascertain whether the alar base cinch suture is effective in controlling the width of the alar base of the nose following Le Fort 1 osteotomy by using a 3D imaging system.

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)
Hospital

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
Surgery: Dentofacial anomalies [including malocclusion]

Interventions
Experimental group will have a clinch suture placed during their operative procedure.
Control group will not.

Intervention Type
Procedure/Surgery

Phase

Not Specified

Primary outcome measure
The amount of change in the width of the alar base of the nose, between control and experimental groups. We will take laser scans at the start and at the end of the treatment periods.

Secondary outcome measures
No secondary outcome measures

Overall study start date
19/04/2006

Completion date
18/07/2007

Eligibility

Key inclusion criteria
1. Patients requiring a Le Fort 1 osteotomy to correct malocclusion
2. Patients concurrently undergoing a course of orthodontic fixed appliance therapy at the time of surgery

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
64

Key exclusion criteria
1. Patients have no previous history of facial trauma
2. Patients do not have a cleft lip and/or palate
3. Patients do not have a craniofacial abnormality
4. Patients are not undergoing a re-treatment procedure
5. Patients have not had previous facial soft tissue surgery
6. No children <16 years old

Date of first enrolment
19/04/2006

Date of final enrolment
18/07/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Orthodontics
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Barts and The London NHS Trust (UK), 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2011		Yes	No