

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/05/2012	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 cinch 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

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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