Randomised controlled trial (RCT) of Pharyngeal Flap and Sphincter Pharyngoplasty in Cleft Palate

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
04/10/2011	Surgery			

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

Study information

Scientific Title

Study objectives

What is the relative effectiveness and morbidity of pharyngeal flap or sphincter pharyngoplasty for correcting velopharyngeal insufficiency

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)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Cleft palate

Interventions

Not provided at time of registration

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

- 1. Pre- and post-operative complications
- 2. Length of time for surgery and for hospitalisation
- 3. Endoscopic and speech findings
- 4. Surgical blood loss

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/1995

Completion date

01/08/2000

Eligibility

Key inclusion criteria

50 patients in each group aged between 3 and 21 years with a repaired cleft palate and clinically diagnosed velopharyngeal insufficiency (VPI)

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Years

Upper age limit

21 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/1995

Date of final enrolment

01/08/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Cochrane Oral Health Group

Manchester United Kingdom M15 6FH

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

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.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive North West (UK)

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	01/09/2005		Yes	No