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

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

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

RHC17021

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