

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
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/10/2011	Condition category Surgery	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 Years

Upper age limit

21 Years

Sex

All

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**

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Executive North West (UK)

Results and Publications

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