ISRCTN48558760 https://doi.org/10.1186/ISRCTN48558760

Fibreoptic endoscopic evaluation of swallowing (FEES): Therapy or Assessment

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/04/2015	Digestive System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Trudi Minns

Contact details
Regional Rehabilitation Unit
North West London Hospitals NHS Trust
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0515163804

Study information

Scientific Title
Fibreoptic endoscopic evaluation of swallowing (FEES): Therapy or Assessment

Study objectives
The hypothesis is that visual & verbal feedback improves the ability of participants to correctly perform specific movements within the pharynx to command. In addition to this I am hypothesising that FEES is a valuable therapeutic tool with regards to comfort, acceptability, time and resources. To date there is no documented evidence supporting the use of Nasendoscopy as a therapeutic tool, despite the obvious clinical benefits.

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)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Digestive System: Deglutition disorders

Interventions
Group 1 Participants of the study will be assigned to one of two groups. All participants will be given information about the anatomy of the pharynx and larynx. This will be done using diagrams. With the aid of the diagram, the participant will then be given information about the precise target movements expected of them. These include: Nasopharyngeal closure, tongue base reaction, vocal fold adduction and the posterior pharyngeal wall. The scope will then be passes transnasally to enable three views the nasopharyngeal port, the pharynx and the larynx.

Participants randomised to group 2 will be positioned to allow viewing of their anatomy. The whole assessment process will be videotaped to allow for inter-rate reliability to be established. The participant will be instructed to attempt to each movement in turn and they will be given 3 minutes to perfect this movement. The participant will then be instructed to attempt to perform

the movement 5 times consecutively. The movement will be scored as present or absent and a score out of 5 will be given. Group 2 participants will be scoped as before to allow the therapist full view of the movements achieved in the pharynx and this that are not. The participant will not however be able to view the monitor. The participants in this group will receive the same amount of feedback that would normally be available for patients receiving therapy with out the help of nasendoscopy. The investigator will provide them with information about the target movements. Group 2 participants will be given a practice period of 3 minutes per movement. The participant will then be asked to perform the target movements 5 times and the researcher will record the consistency with which they are achieved.

As with group 1, all the assessment results will be recorded on to videotape. The assessment time in total should not exceed 20 minutes. Analysis of the results will be achieved using a chi squared statistical test.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Measurement of the target movement. Assessment as to whether or not these movements have been achieved will be rate by the principal investigator and the data will be re-rated by a further therapist skilled in this area

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2002

Completion date
31/03/2006

Eligibility

Key inclusion criteria
Participants will be selected and randomly assigned into two groups. Each group will consist of 10 healthy volunteers with no history of swallowing difficulties. Participants will be recruited predominantly from staff working at Northwick Park Hospital.

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Patients under 18
2. Patients with swallowing difficulties

Date of first enrolment
01/07/2002

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northwick Park Hospital
Harrow
United Kingdom
HA1 3UJ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
North West London Hospitals 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