ISRCTN40298220 https://doi.org/10.1186/ISRCTN40298220

Respiratory muscle training in stroke

Submission date
07/02/2011

Recruitment status
No longer recruiting

Registration date
03/05/2011

Overall study status
Completed

Last Edited
16/09/2016

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Pilot studies to develop and evaluate a muscle strengthening programme to reduce the risk of aspiration and improve outcome in dysphagic stroke patients

Study objectives
The objectives of this research are to inform the design of a larger Phase III study by:
1. Estimating the duration of training required to achieve maximum improvements in inspiratory and expiratory muscle function and peak expiratory flow rates in stroke patients, by extrapolating and refining training methods used in existing studies on patients with other neurological diseases
2. Assessing patient participation and acceptability by quantifying the proportion of screened patients who are eligible for the intervention to those participating, reasons for non-participation, concordance with training schedule and reasons for non-concordance with training
3. Identifying any vascular, cardiac, neurological or systemic consequences of respiratory muscle training that may potentially have an adverse effect on stroke patients because of the higher prevalence of cardiovascular disease or impaired cerebral autoregulation in these patients
4. Estimating the magnitude of effect of inspiratory or/and expiratory muscle training on patient endpoints of aspiration risk, cough generation, chest infections and dependence in activities of daily living
5. Determining elements of a staff training programme and defining patient and stroke characteristics that identify subjects most likely to gain from respiratory muscle strength training in order improve the efficiency and effectiveness of respiratory muscle training.
6. Assessing the relevance and feasibility of delivering respiratory muscle training in NHS settings by using information from above objectives

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wandsworth Research Ethics Committee (South London), 19/05/2010, ref: 10/H0803/32

Study design
Multi-centre randomised controlled pilot study

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 to request a patient information sheet

Health condition(s) or problem(s) studied

Dysphagic stroke

Interventions

A 12 weeks study to investigate the use of respiratory exercises in 60 dysphagic stroke patients. The various interventions are:
1. Expiratory Muscle Training (EMT) will be undertaken using a handheld pressure threshold expiratory muscle strength trainer with a pressure threshold range of 16 to 160 cm H2O
2. Subjects will be instructed to blow as forcefully as possible into the devices mouthpiece after taking a deep breath until the distinct sound of valve opening can be heard
3. They will be asked to maintain this force for as long as possible
4. The researcher will set the training pressure threshold to a sustainable maximum expiratory pressure (approximately 50-60% PEmax) at the beginning of each week. 5. Subjects will train at this pressure for 5 days a week for 4 weeks, completing a minimum of 2 and a maximum of 5 sets per day, separated by at least 1 hour
5. Each set will consist of 10 repetitions with a 1 minute rest between repetitions (20 minutes /per set)
6. A rapid rise in strength of expiratory muscles within the first 4 weeks of EMT with a comparable regimen has been reported in Parkinsons Disease
7. Inspiratory muscle training (IMT) will be undertaken using a pressure threshold device with a pressure threshold range of 7 to 40 cm H2O
8. The valve on this device blocks airflow until the patient generates sufficient inspiratory pressure to open an adjustable springload
valve
9. Subjects will be instructed to exhale fully and take in deep breath as forcefully as possible from the devices mouthpiece until the valve is open and to maintain this pressure as long as possible
10. The researcher will set the training pressure threshold to the sustainable maximum inspiratory pressure (approximately 50-60% PImax) at the beginning of each week
11. Subjects will train at this pressure for 5 days a week for 4 weeks, completing at least 2 and at the most 5 sets per day separated by at least 1 hour
12. Each set will consist of 10 loaded inspirations each with a 1 minute rest between each effort (20 minutes/per set)
13. This regimen has been shown to be well tolerated and effective in improving inspiratory muscle strength in patients with multiple sclerosis
14. Sham training will be provided using the same protocol as the other training groups
15. Inspiratory or expiratory threshold devices will be used in an equal number of subjects but training will be undertaken using a training load of 10-20% PImax or PEmax
16. This approach has been validated in IMT studies in respiratory diseases
17. It was considered necessary to study a group with sham training to control for:
17.1. Natural recovery from stroke, which may otherwise have been interpreted as effects of training
17.2. Unrelated fatigue or adverse events which may be attributed to training
17.3. Learning effects with performing repeated assessments, which may mimic improvements with training

Intervention Type

Other

Phase

Phase II

Primary outcome measure

Assessments of patient outcomes will be undertaken at baseline, completion of training (4 weeks) and at 3 months to assess sustainability of effect. These will include:

1. Assessment of aspiration:
Aspiration will be assessed using videofluoroscopy (VF) undertaken by a speech and language therapist blinded to patient allocation. Patients will be seated in an upright position and different consistencies of food/liquid impregnated with barium will be used. Imaging will be done using lateral projection from the teeth anteriorly to the posterior pharyngeal wall posteriorly. Patients will be scored according to their most unsafe swallow and categorised as: safe (no penetration or aspiration), penetration (entry of material into the laryngeal vestibule without passage through the (true vocal cords), silent aspiration (passage through the cords without cough or accompanying distress) or overt aspiration. The proportion of patients with silent or over aspiration who fail to clear their airways with cough will be used for analysis. Assessment of aspiration will be undertaken in all patients at 4 weeks. Assessment at 3 months will be undertaken only in patients still aspirating at 4 weeks to limit radiation risk.

2. Assessment of function:
Dependence in activities of daily living will be measured using the Nottingham Extended Activities of Daily Living Index, which has been validated in stroke patients.

3. Assessment of respiratory function:
Respiratory assessments will be undertaken masked to allocation. Subjects will be propped up to 45 degrees to ensure that the abdominal muscles are not being used to maintain posture and will wear a nose clip to prevent air leakage. Measurements will be undertaken in accordance with American Thoracic Society and European Respiratory Society guidelines. Forced expiratory volume in the first second (FEV1), forced vital capacity (FVC) and peak expiratory flow rate (PEFR) will be measured using a handheld spirometer and values will be obtained for predicted, actual, and percentage of predicted measurements. The tests will be performed 3 times and the best measurement will be used for analysis. PEmax will be assessed using a handheld digital manometer with a small controlled leak at the exhaust port to prevent glottis closure or recruitment of the facial muscles. Subjects will be asked to take in the maximum possible deep breath and then blow air out as hard and fast as possible for a minimum of 2 seconds. PImax will be measured by asking the subject to exhale fully and then take in the maximum possible deep breath against a closed valve for a minimum of 2 seconds. PEmax and PI max measurements will be repeated up to 10 times and the best 3 within 10% of each other will be averaged for the data analysis. Cough will be measured using a pneumotachograph connected to the subject via a tightfitting mask covering the nose and mouth. Voluntary cough will be initiated by asking subjects to produce the biggest possible cough after inhaling maximally. The process will be repeated until 3 peak flow rates within 10% of each other are achieved. Reflex cough will be induced by nebulising a 20% L-tartaric acid solution through a side port in the face mask with the patient breathing normally during nebulisation. The nebulisation will be performed 3 times for 1 minute, separated by 5 minute intervals. Data from the best recordings of voluntary and reflex cough will be used to assess peak flow rates, expiredvolume and cough volume acceleration, defined as peak airflow/risetime. Chest infection will be defined as temperature greater than 37.5°C on two consecutive measurements or a single measurement of temperature greater than >38.0°C with chest symptoms and one or more of the following: white cell count more than 11 000/mL, pulmonary infiltrate on chest xrays, positive microbiology cultures.

Secondary outcome measures
1. Assessment of participation, acceptability and safety
1.1. Data on the number of stroke patients admitted during the study, and the numbers screened, eligible and participating in the study will be collected. The reasons for exclusion or non participation will be recorded.
1.2. Data on the training provided and difficulties experienced during training instruction or use of equipment will be collected in the trainers log. Information on training pressure thresholds, total number of training sets and repetitions per set will be recorded in the patient log.
1.3. Pre and post training session blood pressure, heart rate and oxygen saturations and adverse events will be collected from the patient training log.

Overall study start date
01/03/2011

Completion date
01/02/2013

Eligibility

Key inclusion criteria
1. Ischemic stroke patients aged between 50 and 80 years with:
1.1. First ever stroke
1.2. Within 1 week of stroke onset
1.3. Moderate severity, defined as NIH stroke scale of 520
2. Videofluoroscopic evidence of aspiration
3. Ability to maintain sitting balance
4. Adequate communication to follow instructions
5. Able to comply with respiratory muscle testing procedures
6. Consent to participation

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Suboptimal blood pressure control (BP greater than 180/100 mm Hg on 3 occasions in last 24 hours)
2. Myocardial infarction, angina or heart failure in the last 3 months
3. Features of raised intracranial pressure on CT scan
4. Pulmonary, neurological (other than stroke) or orthopaedic conditions that adversely affected the respiratory muscle pump

Date of first enrolment
01/03/2011

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	12/04/2014		Yes	No
Results article	results	01/02/2015		Yes	No
Results article	results	01/05/2016		Yes	No