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Investigation to see if cervical spine mobilisation can influence Cervicobrachial Syndrome

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/10/2016	Musculoskeletal Diseases	[ ] Record updated in last year

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
N0191187010

Study information

Scientific Title
Investigation to see if cervical spine mobilisation can influence Cervicobrachial Syndrome

Study objectives
1. To investigate whether a self-management protocol with lateral glide mobilisation is more advantageous than a self-management protocol in isolation for subjects with cervicobrachial syndrome.
2. To establish whether subjects with symptoms of parasthesia, numbness and or weakness in their affected arm in addition to their pain have a different outcome from subjects with pain alone.
3. To determine whether subjects preference is linked with outcome.
4. To determine feasibility and enable thorough planning for a phase III trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 21/09/09: South Staffordshire Local Research Ethics Committee

Study design
Pilot study using a randomised controlled design, with the assessor masked to allocation

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Cervicobrachial syndrome

Interventions
Subjects will receive either lateral glide mobilisations and a self-management programme (Intervention group) or self-management alone (Control group) for the management of cervicobrachial syndrome. Due to the nature of the intervention, it will not be possible to mask subjects and treating physiotherapists to allocation. Assessment will occur at consent, and 6 weeks after initiation of treatment.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Added 21/09/09:
Visual analogue scale for pain

Secondary outcome measures
Added 21/09/09:
1. Neck and Upper Limb Index (NULI)
2. SF36 (RAND)
3. Global Rating of Change Score (GROC)

Overall study start date
01/02/2007

Completion date
01/06/2008

Eligibility

Key inclusion criteria
This study includes patients with any symptoms radiating from the neck to upper limb.

Added 21/09/09:
1. Patients with pain that had started in the neck and spread to one arm (below level of shoulder joint) in a dermatological distribution and been present for more than two months
2. There were no known systemic rheumatological (e.g. Rheumatoid Arthritis RA or Ankylosing Spondylitis AS) or neurological disorders (e.g. Multiple Sclerosis MS, Parkinson's Disease PD)
3. Not involved with any litigation issues regarding neck and arm pain and no symptoms of myelopathy or sinister pathology
4. No previous fractures to the neck or thoracic spine

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Added 21/09/09: 18

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/02/2007

Date of final enrolment
01/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Musculoskeletal Physiotherapy Lead
Burton upon Trent
United Kingdom
DE13 0RB

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - 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
Not defined

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Burton Hospitals NHS Trust (UK), Own Account 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