

Investigation to see if cervical spine mobilisation can influence Cervicobrachial Syndrome

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/10/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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