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The use of cervical collars following anterior cervical discectomy for radiculopathy or myelopathy

Submission date 06/01/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 06/01/2003	**Overall study status** Completed	
Last Edited 31/07/2012	**Condition category** Surgery	

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

M0617

Study information

Scientific Title

Study objectives
Aim of the study was to determine the effect, if any, of wearing a hard collar following Anterior Cervical Discectomy (+/- Grafting) on pain, range of movement and function. No statistically or clinically significant differences were found between collar and no collar wearing groups on any outcomes, although patient compliance was a problem due to the inconvenience of wearing a collar. The need for providing patients with information and
reassurance to mitigate the need for collars is highlighted.

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)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Cervical spondylosis

Interventions
Randomised pre-operatively to either collar-wearing or no collar-wearing group (collars to be worn continuously for 6 weeks following surgery)

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Neck pain and Disability Scale (NPAD)

Secondary outcome measures
Range of Active Cervical Flexion/Extension Movement (degrees) and Function (SF-36)

Overall study start date
01/06/2001

Completion date
31/10/2003

Eligibility

Key inclusion criteria
Patients undergoing single-level anterior cervical discectomy, with or without inter-body grafting, for either radiculopathy or myelopathy, or a combination of both, caused by predominately single-level degenerative disease. This had been confirmed by magnetic resonance imaging (MRI)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
51

Key exclusion criteria
1. Under 16 years of age
2. Acute whiplash or other acute traumatic injury
3. Malignant disease or tumour
4. Concomitant disease (e.g. rheumatoid arthritis) which could influence their recovery
5. Posterior or instrumented surgery
unable to consent to the trial for any reason

Date of first enrolment
01/06/2001

Date of final enrolment
31/10/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Physiotherapy
Southampton
United Kingdom
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Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

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Sponsor type
Charity

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ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (ARC) (UK)

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