

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

Submission date 06/01/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/01/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/07/2012	Condition category Surgery	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Sponsor details
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Sponsor type
Charity

Website
<http://www.arc.org.uk>

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