

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

Protocol serial number

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

Study type(s)

Other

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(s)

Neck pain and Disability Scale (NPAD)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

Study participating centre

Department of Physiotherapy

Southampton

United Kingdom

S016 6DY

Sponsor information

Organisation

Arthritis Research Campaign (ARC) (UK)

ROR

<https://ror.org/02jkpm469>

Funder(s)**Funder type**

Charity

Funder Name

Arthritis Research Campaign (ARC) (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration