Managing Injuries of the Neck

Submission date	Recruitment status No longer recruiting	Prospectively registered		
02/11/2004		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
02/11/2004	Completed	[X] Results		
Last Edited 25/02/2013	Condition category Injury, Occupational Diseases, Poisoning	[] Individual participant data		

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

Protocol serial number HTA 02/35/02

Study information

Scientific Title

Acronym

Study objectives

To estimate the clinical and cost effectiveness of a stepped care approach following acute injury.

A related study "Managing Injuries of the Neck Trial - Incentive" is registered with ISRCTN61305297.

Please note that, as of 11/05/2009, the anticipated end date has been updated from 31/10/2008 to 31/03/2009.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by UK Trent Multicentre Research Ethics Committee and by the Local Research Ethics Committee and the Research and Development Committee of each participating centre.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute neck sprain (whiplash)

Interventions

Stepped care approach.

- 1. Step One: The Whiplash Booklet versus usual care advice in Accident and Emergency (A&E)
- 2. Step Two: In patients with symptoms persisting at 3 weeks (WAD Grade I-III), supplementary treatment comprising either a package of physiotherapy treatments and re-enforcement of advice versus re-enforcement of advice provided at the initial A&E contact only
- 3. Step Three: The combined effect of the various treatments using a 2 by 2 factorial design

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Return to normal function will be assessed using Neck Disability Index

Key secondary outcome(s))

SF-12® Health Survey, Euroqol EQ-5D

Completion date

Eligibility

Key inclusion criteria

- 1. People with Acute whiplash (<6 weeks), Whiplash Associated Disorder (WAD) grades I-III
- 2. Patients with persisting symptoms three weeks after their Emergency Department attendance

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Age below 18
- 2. Fractures or dislocations of the spine and other bones
- 3. Head injuries with more than a transient loss of consciousness or with a Glasgow coma score of 12 or less at any stage of their assessment in hospital
- 4. Admission to in patient services
- 5. Severe psychiatric illness

Date of first enrolment

01/11/2004

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Warwick Emergergency Care & Rehabilitation

Coventry United Kingdom CV4 7AL

Sponsor information

Organisation

Department of Health (UK)

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2009		Yes	No
Results article	results	01/09/2012		Yes	No
Results article	results	16/02/2013		Yes	No
Protocol article	protocol	26/01/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes