

Managing Injuries of the Neck

Submission date
02/11/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date
02/11/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ 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

Study website

<http://www2.warwick.ac.uk/fac/med/healthcom/emergencycare/research/whiplash/>

Contact information

Type(s)

Scientific

Contact name

Prof Sarah Elizabeth Lamb

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Acronym

MINT

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Return to normal function will be assessed using Neck Disability Index

Secondary outcome measures

SF-12® Health Survey, Euroqol EQ-5D

Overall study start date

01/11/2004

Completion date

31/03/2009

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

Age group

Adult

Sex

Both

Target number of participants

4,800 patients in first step and 600 patients in second step

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

England

United Kingdom

Study participating centre

Warwick Emergency Care & Rehabilitation

Coventry

United Kingdom

CV4 7AL

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House

Quarry Hill

Leeds

United Kingdom

LS2 7UE

Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/en/index.htm>

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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

Study outputs

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