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Warwick Spinal Immobiliser

Submission date 20/09/2012	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/12/2012	**Overall study status** Completed	
Last Edited 04/06/2018	**Condition category** Injury, Occupational Diseases, Poisoning	

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
12376

Study information

Scientific Title

Warwick Spinal Immobiliser - development and initial trial of prototype spinal immobilisation device

Study objectives
Traumatic spinal cord injury (SCI) is rare but has devastating consequences on the quality of life of patients and their families. Figures from the UK are difficult to obtain, but we estimate that 100,000 patients in England receive spinal immobilisation each year. As modern trauma care appropriately assumes that injury is present until excluded, this creates a huge demand for effective spinal immobilisation.

Current methods usually involve a semi-rigid collar with head blocks and tape, but we and others have shown that this does not adequately immobilise the neck, allowing movement of the spine risking further injury. The rigid collar prevents opening of the mouth leading to feelings of claustrophobia, and potential danger of inhaling vomit. If the patient stops breathing, the collar must be removed to enable insertion of a breathing tube, increasing the risk of spinal cord damage. Pressure of the collar on the back of the head can cause pressure sores, and on the root of the neck can increase pressure within the brain, worsening any existing head injury.

We have invented a device providing better immobilisation without preventing mouth opening, leading to a safer experience. It can be applied before the patient is removed from a vehicle increasing safety for patient and paramedic, and can be left on during X-rays and other investigations.

We will train paramedics to use the device and ask volunteers to compare it to current methods by measuring movement of the spine, ability to open the mouth for normal breathing, ability to intubate, measuring risk of pressure sores, and conducting interviews and observations to gather the experience of volunteers and paramedics. Following feedback we will redesign and retest the device, and perform MR scanning that uses magnetic fields and a computer to measure movement between individual neck bones. We believe we have a device that is effective, more comfortable and safer for patients and easier for paramedics to use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - South, 31/05/2012, ref: 12/WM0098

Study design
Non-randomised observational qualitative study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Injuries and Emergencies, Anaesthetics

Interventions
We are testing two versions of the prototype device on healthy volunteers to measure the degree of immobilisation of the head in relation to the shoulders, and the spinal cord, compared to two currently-used devices. We are obtaining the opinions of paramedics trained to apply the device on how it can be improved, and how it compares to their normal experience of applying spinal immobilisation. We are obtaining the opinion of anaesthetists on ease of intubation of a manikin wearing the new and comparator devices.

Intervention Type
Device

Primary outcome measure
Prototype testing

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/07/2012

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. Healthy volunteers employed by the ambulance service or medical school, or training as a medical student and a willingness to take part in the study
2. Male and female participants
3. Aged 18 - 60 years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 140

Key exclusion criteria
1. For the first prototype testing we shall exclude people who have known neck problem or history of neck surgery, injury to the neck within the previous 12 months
2. Any condition resulting in restriction of neck movement, known claustrophobia, and, for the second prototype testing involving MR scanning
3. People with metallic implants, pacemaker
4. People who are, or may be, pregnant
5. Refusal to sign the confidentiality agreement will be an exclusion criterion

Date of first enrolment
01/07/2012

Date of final enrolment
31/05/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Warwick
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
Gibbet Hill Road
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Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
NIHR - Invention for Innovation (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