Evaluation on the level of discomfort and restriction on activities of daily living (ADLs) whilst C-spine immobilised in a spinal collar after C-spine injury.

MAIN SPONSOR: Imperial College Healthcare NHS Trust
FUNDERS: n/a
STUDY COORDINATION CENTRE:
NRES reference:

Protocol authorised by:

Name & Role	Date	Signature

Study Management Group

Chief Investigator: Dr Michael Fertleman

Co-investigators: Dr Annabelle Lee, Dr Louis Koizia

Statistician: n/a

Study Management:

Study Coordination Centre *n/a*

For general queries, supply of study documentation, and collection of data, please contact:

Study Coordinator:
Address:
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Clinical Queries

Clinical queries should be directed to Dr Michael Fertleman who will direct the query to the appropriate person.

Sponsor

Imperial College Healthcare NHS Trust is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Joint Research Compliance Office
Imperial College London & Imperial College Healthcare NHS Trust
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Funder

None required

This protocol describes the assessment of comfort in a spinal collar study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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Glossary of Abbreviations

ADLs	Activities of daily living
C-spine	Cervical spine

Keywords: Spinal collar, pain, activities of daily living.

Study Summary

Title	Assessment of comfort in a spinal collar
Design	Observational study
Aims	Determine the level of discomfort produced by the spinal collar in adults with a C-spine (neck) injury. Establish whether the spinal collar impedes activities of daily living
Outcome measures	Visual analogue scale for pain Neck disability index questionnaire
Population	Adults aged 18yrs and older
Eligibility	Patients who are wearing a spinal collar for acute neck injury.
Duration	12 months

1. Introduction

1.1 Background

Through our own experience we have noticed that older people find wearing spinal immobilisation collars uncomfortable and that these collars restrict activities of daily living. For this reason they are poorly tolerated and can hamper progress therapy thereby delaying recovery.

1.2 Rationale for current study

Limited research has been performed in this area; our proposed study will assess the comfort of the spinal collar in the young and old who are wearing the collar due to traumatic injury. We will also assess the ability to complete activities of daily living whilst wearing the collar.

2. Study Objectives

a) Determine the level of discomfort produced by the spinal collar adults with a C-spine (neck) injury.
b) Establish whether the spinal collar impedes activities of daily living

3. Study design

Observational study using patient questionnaires.

3.1 Participant identification

Patients will be identified daily at the morning Major Trauma Meeting where all new admissions are discussed.

3.2 Methodology

A member of the research team will approach all patients meeting the inclusion criteria on the ward. A patient information leaflet will be provided and at least 24hrs will be allowed prior to consenting to the study. Patient will be required to provide written consent prior to participation.

The following demographic information will be collected: age, sex and ethnicity. The study will also record the injuries sustained following trauma and prescribed analgesia with records of the most recent time and dose administered.

Any C-spine (neck) imaging performed as part of standard clinical care will be anonymised by the PACS team before being downloaded to CD. This CD will be hand delivered to an expert in Imperial College to allow measurements of angulation to be analysed.

Participants will be asked to fill out a questionnaire on five occasions during their inpatient treatment. The questionnaire will consist of the visual analogue score (validated pain scoring system for scoring pain severity from 0-10) and the neck disability index (10 point questionnaire).

The time points for the questionnaire to be filled out will be:
1. In retrospect for pre-admission state
2. On admission
3. On walking
4. On eating
5. On discharge

The study follows the patient journey including long -term follow up (up to 120 days following admission).

3.3 Study outcome measures
Visual Analogue Scale Scoring (pain severity score) and Neck Disability Index questionnaire (functional assessment) scores

4. Participant Entry

4.1 Pre-registration evaluations
Demographic values (age, sex, ethnicity, functional status [assessed by neck disability index]), documentation of injuries in addition to C-sine injury.

4.2 Inclusion criteria
1. All patients aged 18yrs and over with a C-spine injury immobilised in a spinal collar
2. Patients must be nursed on Major Trauma Ward
3. Ability to give informed consent to participate in the study.

4.3 Exclusion criteria
1. Patients under 18yrs age
2. Patients who lack capacity to consent for entry into the study
3. Patients who are receiving level 2 (High dependency unit) or level 3 (Intensive care unit) clinical care
4. Patients who are unable to complete the visual analogue score or questionnaire due to co-existent severe hearing and visual impairment. Severe hearing impairment will be defined as unable to hear the researcher with hearing aids if required. Severe visual impairment will be defined as being unable to read the patient information sheet even with visual aids.
5. Patients unable to understand the patient leaflet in English.

4.4 Withdrawal criteria
1. Loss of capacity during the study will result in automatic suspension from the study until capacity is regained.
2. Participants may choose to withdraw from the study at any time. Withdrawal will not affect the clinical care delivered.

5. Adverse Events
n/a – observational study

6. Assessment and follow up
Participants will receive standard clinical follow up.

7. Statistics and Data Analysis
Data analysis will be via standard parametric statistical analysis. Data will be kept for a maximum of 10 years following completion of the study.

8. Regulatory Issues

8.1 Ethics approval
The study has gained support from **[insert ethics board].** Every patient must hold capacity to consent to the study and have provided written consent.

8.2 Consent
Participants must have capacity to consent. Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and at least 24hours allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

Consent will be taken by a physician who holds a Good Clinical Practice (GCP) qualification and is qualified to assess capacity for consent. Should it come to the attention of the clinical or research team (research team form part of the clinical team) that a patient has lost capacity the participant will be suspended from the study. On re-gaining capacity participants must be re-consented into the study using the original consent form and patient information sheet.

8.3 Confidentiality
The research team also forms part of the standard care team. Patient records will therefore, only be accessed by the standard care team.

Paper documentation i.e. signed consent forms will be kept in a filling cabinet within a locked office. All participants will be allocated a non-identifiable study number on consenting to the study. Any written documentation (patient questionnaires) following allocation of a study number will use this number only for identification. Anonymised data collected from the study will be analysed by the research team.

Any imaging of the neck done as part of standard clinical care will be anonymised by the on site PACS team prior to being downloaded onto a CD and hand delivered an expert at Imperial College to allow analysis of measurements of angulation. Scientists will only be analysing anonymised scans and will not have access to any confidential personal data.

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the General Data Protection Regulation for health and care research.

8.4 Indemnity
Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Litigation Authority for NHS Trusts in England, which apply to this study.

8.5 Sponsor
Imperial College Healthcare NHS Trust will act as the main Sponsor for this study.

8.6 Funding
No external funding has been applied for. Patients will not receive any payment for participation.

8.7 Audits
The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care

9. Study Management
The day-to-day management of the study will be co-ordinated through Dr Michael Fertleman.

10. Publication Policy
Completed research will be submitted to a peer reviewed journal for publication

11.References
Karason S, Reynisson K, Sigvaldason K, Sigurdsson GH. 2014. Evaluation of clinical efficacy and safety of cervical trauma collars: differences in immobilization, effect on jugular venous pressure and patient comfort. *Scand J Trauma Resusc Emerg Med.* 22, p37.

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