Comparison of measurements of the cervical spine in adults with and without immobilisation.

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STUDY COORDINATION CENTRE:
NRES reference:

Protocol authorised by:

Name & Role	Date	Signature

Study Management Group

Chief Investigator: Dr Michael Fertleman

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Statistician: n/a

Study Coordination Centre *n/a*

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Clinical Queries

Clinical queries should be directed to Dr Annabelle Lee 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
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Funder

None required

This protocol describes the assessment of measurements of angulation of the C-spine 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 UK Policy Frame Work for Health and Social Care Research. 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

C-spine	Cervical spine
MRI	Magnetic resolution imaging

Keywords: Comfort, measurements of angulation, MRI, spinal collar

Study Summary

Title	Comparison of measurements of the cervical spine in adults with and without immobilisation.
Design	Controlled study without randomisation
Aims	Determine if a young persons neck is the same shape as an older persons neck. Determine if a spinal collar alters the shape of the neck. Assess the level of discomfort in a spinal collar
Outcome measures	Measurements of angulation of the C-spine on MRI scan Visual analogue scale for pain
Population	Adults aged 18yrs – 30yrs and 70yrs and over.
Eligibility	Persons who have no discomfort in the neck, no known medical condition and no previous injury affecting the neck or spine.
Duration	12 months

1. Introduction

1.1 Background

Through our own experience we have noticed the external shape of an older persons neck appears to be different to that of a younger person with older patients necks being angled towards the floor rather than upright even when they do not have an obvious curvature (kyphosis) to the rest of their spine. We have also noticed that older patients do not tolerate wearing a spinal collar as well as younger ones and therefore would like to assess the level of comfort when wearing a spinal collar in healthy volunteers. This will help us to assess whether older patients do not tolerate the spinal collar as well as younger patients due to pain from their injury or from the collar itself.

1.2 Rationale for current study

Limited research has been performed in this area; our proposed study will assess the difference in the shape of the neck when comparing the younger population to the older population. Additionally we would like to assess whether the shape of the neck changes when wearing a spinal collar and how comfortable the device is to wear.

2. Study Objectives

a) Determine if a young persons neck is the same shape as an older persons neck.
b) Determine if a spinal collar alters the shape of the neck.
c) Assess the level of discomfort in a spinal collar

3. Study design

Non-randomised controlled study

3.1 Participant identification

Recruitment of volunteers will take place via poster advertisements displayed in public areas at St Mary's Hospital, Paddington. Interested persons will be able to contact the research team via the email address written on the poster. Following initiation of contact with the research team potential participants will be sent a patient information leaflet, which will include necessary requirements for inclusion and exclusion criteria.

3.2 Methodology

This is a prospective study aiming to assess the shape of the neck in adults. In addition the study will look at the shape of the neck in a spinal collar and the comfort while wearing a spinal collar.

Age of participants to be recruited: 18yrs and over - 30yrs and 70yrs and over.
Adult research participants will be recruited from the general public via poster. Interested persons will be asked to contact the research team via email. Patient information leaflets and an MRI safety questionnaire will be accessible via email correspondence.

On making contact with the research team interested persons will have the opportunity to ask any questions prior to agreeing to the study with a minimum of 24hrs between having the opportunity to discuss participation with the research team and agreeing to the study.
Participants must consent to the GP being contacted with the scan report to ensure appropriate record keeping especially in the event of an incidental finding.

Participants will be required to attend the hospital for half a day on a specified weekend day.
On arrival participants will be asked to fill in a validated questionnaire (Visual Analogue Score) about the level of discomfort in their neck.
Participants will need to fill in a safety questionnaire prior to the neck scan and change into a hospital gown for the scan. Participants will undergo a neck scan, which requires the participant to spend approximately 5 minutes lying flat in the scanner.
The participant will then have a spinal collar fitted by an expert (equivalent to that fitted in standard clinical practice) and spend one hour wearing the collar.
Following one hour wearing the spinal collar the participants will be asked to repeat the same questionnaire regarding comfort and a second neck scan with participants wearing the spinal collar will be performed (requires the participant to spend approximately 5 minutes lying flat in the scanner).

Scans will be reported by a medical expert (Radiologist) and reports sent to the GP. The annonymised scans will also be analysed by expert scientists at Imperial College for measurements of angulation.

3.3 Study outcome measures
Measurements of angulation of the neck taken from MRI scans.
Visual Analogue Scale Scoring (pain severity score)

4. Participant Entry

4.1 Pre-registration evaluations
Demographic values (age, sex, ethnicity).

4.2 Inclusion criteria
1. Persons aged 18yrs and over to those aged 30yrs
2. Persons aged 70yrs and over
3. Ability to give informed consent to participate in the study

4.3 Exclusion criteria
1. Persons under 18yrs of age and those aged 31yrs -69yrs
2. Persons who lack capacity to consent for entry into the study
3. Persons who are unable to complete the visual analogue score or questionnaire due to co-existent severe hearing and visual loss. 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.
4. Persons unable to understand the information leaflet in English.
5. Those with current neck pain, known previous C-spine injury or known medical condition affecting the spine.
6. Persons who do not pass the safety questionnaire to undergo an MRI scan
7. Persons who are knowingly unable to tolerate an MRI scan due to claustrophobia
8. Persons who are unable to transfer to the scanner table independently
9. Persons unable to lie flat and still for 10 minutes
10. Persons who do not give consent to the GP being informed of scan results.

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

The study does not involve any invasive intervention, spinal collars and MRI scans are used in usual clinical practice therefore we do not anticipate any adverse events as a result of participation in the study.

6. Assessment and follow up

All MRI scan reports will be sent to the participants General Practitioner (GP). In the event of any adverse incidental findings a clinic appointment will be offered at St Mary's Hospital, Paddington. There will be no routine follow up for participants.

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 Coordination Centre has obtained approval from the xxx Research Ethics Committee (REC) and Health Regulator Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

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. Participants must consent to their GP being

sent a copy of their MRI scan result. The right of the person to refuse to participate without giving reasons must be respected. All participants are free to withdraw at any time from the study.

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.

8.3 Confidentiality
The Chief Investigator will preserve the confidentiality of participants taking part in the fulfil transparency requirements 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. Participants will not receive any payment for participation. Participants will be offered a picture of their neck imaging.

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 and the Research team.

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

11.References
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