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Does a neck collar keep the head and neck still when carrying a player off the football pitch on a stretcher?

Submission date
09/03/2021

Recruitment status
No longer recruiting

Registration date
11/03/2021

Overall study status
Completed

Last Edited
17/01/2022

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In sport, a severe neck injury is rare but potentially very serious. Many sporting bodies provide mandatory emergency care training for medical staff, which includes how to assess and safely remove an athlete with a suspected neck injury from the field of play with either minimum head and neck movement or no movement at all. This widely accepted procedure to keep the neck still includes fitting a neck collar, but it is debatable whether the collar is necessary to provide sufficient head and neck support. Indeed, it has been suggested that fitting a collar to an injured player may result in an undesirable increase head and neck movement. This study's aim is to see whether there is any difference in head and neck movement from using a collar or not, when a player is removed from the field of play using a standard immobilization procedure. The results from this study will inform clinical practice in this important area of athlete care.

Who can participate?
Adults who are elite footballers at an English Premier League football club.

What does the study involve?
Test sessions will be performed over a period of 21 days in an indoor elite sporting facility. Each participant will act as their own control. The standard cervical spine immobilisation procedure will be applied to each participant with the two conditions - ‘cervical collar’ and ‘no cervical collar’ applied in a randomized order.

Possible risks and benefits of participating?
To ensure there is no risk of identifying the participants, any information we collect which may identify players will remain confidential, restricted and player confidentiality will be maintained at all times. All data will be made anonymous by using a unique study. There are no foreseen physical risks from the study. The benefits to the participants will be regarded as long term, in that the use (or not) of a cervical collar in sports clinical practice will ensure enhanced care for football players.

Where is the study run from?
The AON Training Complex, Carrington, Manchester (UK)

When is the study starting and how long is running for?
January 2021 to September 2021

Who is funding the study?
Manchester United Football Club Ltd (UK)

Who is the main contact?
Professor Michael Callaghan, michael.callaghan@manchester.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ID 1403

Study information

Scientific Title
The effect of a cervical collar on head and neck movement during emergency spinal immobilisation and extrication procedures in elite football (soccer) players. The Range of movement Evaluation using Stabilisation Techniques during extrication In Cervical Trauma (RESTRICT)

Acronym
RESTRICT

Study objectives

A cervical hard collar used as part of a spinal immobilisation and extrication procedure will show a reduction in head and neck movement measures compared to the same procedure without a collar.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2021, University of Salford (Research & Knowledge Exchange, Maxwell Building, University of Salford, Manchester, M5 4WT, UK; no telephone number provided; ethics@salford.ac.uk), ref: 1403

Primary study design
Interventional

Study design
Interventional randomized cross over trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthy participants simulating acute neck injury requiring cervical immobilisation and extraction from the field of play

Interventions
Participants will act as their own controls. Each will receive in a random order a ‘cervical collar’ or ‘no collar’ as part of the simulated exercise. Measures of head and neck movement will be taken during the procedure using sensors placed on the head and chest.

Each participant (assuming the role of an injured player) will adopt a supine lying position on artificial turf and a standardised immobilisation and extraction procedure will be applied. This will be divided into 12 components to facilitate the analysis and ensure a consistent protocol throughout. The procedure will take approximately 15 minutes for each condition for each participant (total time 30 minutes). Participants will act as their own controls. Each will receive in a random order a ‘cervical collar’ or ‘no collar’ as part of the simulated exercise. Randomized order created using the Research Randomizer online tool (www.randomizer.com).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cervical collar

Primary outcome(s)
Head and neck movement measured during the entire procedure and will include 3-dimensional movement of head and neck in flexion, extension, rotation, side flexion, yaw, pitch and tilt and acceleration (measured during each condition). A Wireless 8 channel Delsys Trigno EMG unit

(Delsys Inc, Natick, Massachusetts, USA) will be utilised. This device has 9 axis inertial measurement capability allowing acceleration, rotation and magnetic field information. The acceleration data has a span of +- 2g to +-16g. A three camera motion analysis system (Qualisys OQUS 300) will be used to collect three-dimensional range of motion of markers placed on the head and torso of the individual.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
20/09/2021

Eligibility

Key inclusion criteria
Elite football players under contract at an English Premier League Football Club.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
Any player who is being treated for a head or neck injury or ongoing cervical pain or radiculopathy.

Date of first enrolment
21/04/2021

Date of final enrolment
20/09/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

AON training facility
Isherwood Road
Carrington
Manchester
United Kingdom
M31 4BH

Sponsor information

Organisation
Manchester United Football Club

Funder(s)

Funder type
Other

Funder Name
Manchester United FC

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from Prof. Michael Callaghan Head of Medical Research & Innovation, Manchester United FC; email: michael.callaghan@manutd.co.uk The data will be in a data spreadsheet format and will be available after the study's publication in a peer reviewed journal. We would consider making the data available to share after production of ethical approval and a guarantee of data anonymisation, and recognition and acknowledgment of the origin of the data and of the original research team and participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/12/2021	17/01/2022	Yes	No
Protocol file		10/03/2021	11/03/2021	No	No