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

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered	
09/03/2021		[X] Protocol	
<b>Registration date</b> 11/03/2021	Overall study status Completed Condition category	Statistical analysis plan	
		[] Results	
Last Edited		Individual participant data	
17/01/2022	Injury, Occupational Diseases, Poisoning	[_] 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

**EudraCT/CTIS number** Nil Known

IRAS number

**ClinicalTrials.gov number** Nil known

Secondary identifying numbers 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

**Study design** Interventional randomized cross over trial

**Primary study design** Interventional

Secondary study design Randomised cross over trial

**Study setting(s)** Other

Study type(s) Treatment

## Participant information sheet

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

## 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 measure

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.

## Secondary outcome measures

There are no secondary outcome measures

Overall study start date 01/01/2021

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

**Age group** Adult

**Sex** Male **Target number of participants** 34

**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** England

United Kingdom

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

# Sponsor information

**Organisation** Manchester United Football Club

Sponsor details AON Training Facility Carrington Manchester United Kingdom M31 4BH +44 (0)161 8688750 steve.mcnally@manutd.co.uk

Sponsor type

Other

Website https://www.manutd.co.uk

# Funder(s)

**Funder type** Other

Funder Name Manchester United FC

# **Results and Publications**

## Publication and dissemination plan

Regardless of negative or positive outcomes, findings will be published in a peer-review journal and presented at scientific conferences. We will use several approaches for dissemination of the results including social media platforms and podcasts). These will be used to disseminate and communicate results to medical and academic staff internal and external to the Club, and also to the key stakeholders delivering ATMMiF or equivalent sports trauma management courses. These approaches will include utilisation of social media platforms, podcasts in addition to the presentation and publication of the results as stated above.

#### Intention to publish date

21/04/2022

## 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 file		10/03/2021	11/03/2021	No	No
Protocol article		27/12/2021	17/01/2022	Yes	No