Plan Overview

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Title: The CONcussion in non-aThletes; Assessment of CogniTion and Symptomatology (CONTACTS) study: An exploratory cohort study investigating the utility of concussion assessment tools in concussed vs control adult participants

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Project abstract:

Introduction:

Concussion is a complex pathophysiological process with a wide range of non-specific signs and symptoms. There are currently no objective diagnostic tests to identify concussion, and diagnosis relies solely on history and examination. Recent research has identified a unique panel of micro-RNAs (miRNAs) that distinguish between concussed and non-concussed rugby players. This study aims to assess the diagnostic utility of salivary miRNAs in concussion for a sample of NHS patients, and whether well-established sports-related concussion (SRC) assessment tools may be translated into the Emergency Department (ED).

Methods and analysis:

CONTACTS is a single-centre, prospective, two-phase cohort study. The concussed cohort will consist of participants with maxillofacial trauma and concurrent concussion. The control cohort will consist of participants with isolated limb trauma and no evidence of concussion. Saliva samples will be taken to identify the presence of miRNAs. The SRC assessments being investigated include the Sports Concussion Assessment Test version 5 (SCAT5), the Immediate Post-Concussive Assessment and Cognitive Test (ImPACT) and the ImPACT Quick. Follow up will be at 24-48 hours, 14 days and 6 months.

Ethics and dissemination:

Ethical approval was granted in February 2021 by the West Midlands - Coventry & Warwickshire Research Ethics Committee (ref 20/WM/0299).

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The CONcussion in non-aThletes; Assessment of CogniTion and Symptomatology (CONTACTS) study: An exploratory cohort study investigating the utility of concussion assessment tools in concussed vs control adult participants

Data description

What types of data will be used or created?

12.3 Baseline data

All participants will have a medical history and clinical examination as part of routine standard of care and the following are to be recorded in the Case Report Form (CRF):

Standard of care

 Patient demography
 Past medical history (including co-morbidities and medications)
 Injury related events (time of injury, mechanism of injury, subsequent signs/symptoms)
 Neurological status
 Diagnosed injury
 CT head findings (only if performed as standard of care)
 Medications received

Study related data

 ImPACT Quick composite scores
 SCAT5 domain scores
 Contact details (telephone and email address)
 Educational level (number of years of education completed)
 Diagnosis of learning disability or Attention Deficit Hyperactivity Disorder
 Level of intoxication (number of units of alcohol consumed as reported by the participant)
 History of concussion or other head injury

Study related sample

 Saliva sample

12.4 Study assessments

24-48 hrs

 ImPACT composite scores
 SCAT5 domain scores
 Operative interventions
 Neurological status
 Presence or absence of PTA
 CT head findings (only if performed as standard of care)
 Saliva sample

14 days

 ImPACT performed remotely (link sent via email)
 SCAT5 symptoms checklist (via telephone)

6 months

 SCAT5 symptoms checklist (via telephone)

 Functional data (return to work, return to fitness)

12.5 Qualitative assessment

A qualitative telephone interview will be conducted at 6 months following enrolment. Where possible the interviewer will be the same researcher who has had prior contact with the patient, either in-hospital or via telephone. This consistency is something that the TAG PPIE group felt was important from the participant point of view and would lead to a more productive qualitative interview as rapport would already be established. Given the nature of qualitative interview, the process cannot be blinded. The format will be of “in-depth semi-structured” interviews on an individual basis. These are interviews organised around a set of predetermined open-ended questions, with other questions generated from subsequent dialogue between interviewer and interviewee. An “interview guide” will be used that will contain a list of questions and topics that should be covered over the course of the interview. This will be a list of short questions, followed by prompts and grouped by topic.

The interviews will be conducted via telephone and recorded for subsequent analysis using NVivo analysis software. Initial written consent will include the recording of such interviews and subsequent verbal consent will be obtained again prior to recording. Reporting of qualitative data will reported according to Consolidated criteria for Reporting Qualitative Research (COREQ) guidelines.

12.6 Collection, storage and testing of saliva samples

The samples will be collected in CP-190 (DNA genotek) saliva collection pots containing a proprietary miRNA stabilising solution. In these pots samples will be stable at room temperature for 8 weeks and will be transferred to the laboratory within 1 week of collection to comply with Human Tissue Act regulations. The samples will be transported to the laboratory at the University of Birmingham (UoB) and stored in the -80 degrees Robert Aitken 3rd floor freezer room. Following this they will be processed in line with the sample manufacturer’s guidance to allow freezing and storage. A profile of 23 different miRNAs will be analysed using standard qPCR technique. Once the study has been completed all samples will be destroyed.

How will the data be structured and documented?

See previous question

Data storage and archiving

How will your data be stored and backed up?

15.1 Data collection tools and source document identification

Data will be collected from medical records (paper or electronic) and recorded in an approved study case report form (CRF). The CRFs must be completed, dated and signed by the investigator or designee in a timely manner. It remains the responsibility of the investigator for the timing, completeness, legibility and accuracy of the CRF pages. The CRF will be accessible to trial co-ordinators, data managers, the investigators, auditors and inspectors where required. All CRF pages must be clear, legible and completed in black ink. Any errors should be crossed with a single stroke so that the original entry can still be seen. Corrections should be inserted and the change dated and initialled by the investigator or designee.

The following documentation will be considered as source data:

- Patient medical notes (paper and/or electronic as applicable)
- Screening logs
- Informed consent forms
- Qualitative interview transcripts
- SCAT5 sheet
- CRF will contain some source data; educational level, intoxication level, ImPACT Quick composite scores, ImPACT composite scores, SCAT5 symptoms checklist and score

15.2 Data handling and record keeping

An electronic database will be created and stored on an NHS computer with password encryption in a locked office of the Surgical Reconstruction and Microbiology Research Centre. No patient identification details other than study number will be included in the hard copies. Where identifiable data is requested for the SCAT5 form this will be replaced by study number only. Contact details will be kept in a separate log and will not be included on any hard copies. Data will only be transferred via encrypted NHS email, and never with patient identifying details. Data will only be transferred between study investigators for the purpose of data analysis and interpretation.

CRFs will be stored in a locked office of the Surgical Reconstruction and Microbiology Research Centre.

The ImPACT clinical reports are encrypted and stored centrally online, accessed via a password protected account. ImPACT security and privacy standards are compliant with HIPAA/HITECH and PIPEDA as well as the EU privacy directive. All fields in the database that store personally identifiable information are encrypted usingAES-128 bit encryption. However, no personal identifiable information will be inputted into the ImPACT assessments, study number will be used instead of name.

15.3 Access to data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections- in line with participant consent.

Is any of the data of (ethically or commercially) sensitive nature? If so, how do you ensure the data are protected accordingly?

Yes, there will be personal identifiable data

17.5 Data protection and patient confidentiality

All stored patient data will only include details of study number, age and gender. A central master list of study number against hospital identification number will be held by the trial coordinator on an NHS encrypted computer in the research office of the Surgical Reconstruction and Microbiology Research Centre. Consent will be taken for these details to be collected and stored.

Where will your data be archived in the long term?

15.4 Archiving

Study documentation and data will be archived for at least 15 years after completion of the study. The CI or designee must maintain adequate and accurate records to enable the conduct of the study to be fully documented and the study data to be subsequently verified.

After study closure the CI will maintain all source documents and study related documents. The SRMRC will maintain specific study related documents. All source documents will be retained for a

minimum for 15 years following the end of the study. The Sponsor will authorise and advise of the archiving requirements as part of the site closure process.

Data sharing

Which data will you share, and under which conditions? How will you make the data available to others?

15.3 Access to data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections- in line with participant consent.

Where journals require open access to raw data, these will be anonymised prior to any submission to a data repsoitory.