Heading in football: impact on neural blood biomarkers

Published: 26-07-2023
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To determine the potential impact of ball heading in football on brain integrity as assessed by blood biomarkers for neural damage in a real-world setting.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Encephalopathies
Study type	Observational invasive

Summary

ID

NL-OMON53582

Source
ToetsingOnline

Brief title
HEADLINE

Condition

- Encephalopathies

Synonym
brain damage, Neurodegeneration

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Koninklijke Nederlandse Voetbalbond (KNVB)

Intervention

Keyword: Biomarker, Football, Heading, Neural damage

Outcome measures

Primary outcome

The main study parameter is the change in concentration of neurofilament light after playing a football match with naturalistic heading exposure.

Secondary outcome

The secondary study parameters are the change in concentration of GFAP, p-Tau, S100B, NSE and beta-synuclein in blood after playing a football match with naturalistic heading exposure. Other study parameters are demographic variables, medical history, heading characteristics, exercise intensity, and genetic risk factors for neurodegenerative disease.

Study description

Background summary

With an estimated 265 million active players around the world, football (soccer) is the most popular sport worldwide. Football is unique in that it is the only sport that allows intentional use of the head to play the ball.2 There is growing concern about possible harmful effects of heading for the brain due to repetitive head impact, in both amateur and elite football players. Nevertheless, to date there is limited evidence for either acute or cumulative effects of heading on the brain of active football players. Biomarkers of neural damage have proven diagnostic value for brain damage caused by traumatic brain injury and neurodegenerative disease, and therefore represent a promising method to investigate the impact of heading exposure on brain integrity. Existing studies lack sufficient sample sizes to detect small effects and have often not assessed a realistic exposure to ball heading in a real-world setting. Moreover, the biomedical field has recently brought forward novel and biomarkers of neural damage. Taken together, the field is in need of longitudinal studies that investigate the impact of a naturalistic ball heading

exposure on brain integrity with substantial sample sizes.

Study objective

To determine the potential impact of ball heading in football on brain integrity as assessed by blood biomarkers for neural damage in a real-world setting.

Study design

A prospective observational study

Study burden and risks

Burden
Participants will be requested to participate in the following measurements:
1. Fill in an intake questionnaire (duration: 10 minutes)
2. Provide 2-3 blood samples of 14-20 ml, in total 34-48ml (duration: 20-35 minutes)
3. Play a football match while wearing a Local Positioning System sensor and heart rate sensor (duration: 105 minutes)

Risks and benefits
The risks of participation in this observational study are considered negligible (also see attachment *Risk Assessment*). Participants do not have a direct benefit of participation.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100DD
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100DD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Member of the KNVB
- 18 years or older
- Male
- Self-reported fitness to play 70-90 minutes

Exclusion criteria

- Sustained a head injury in the last year
- History or current neurological condition
- Regular participation in other contact sports (e.g. rugby, American football, ice hockey, fighting sports)
- (Former) military personnel with a history of fighting/blast exposure

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-08-2024
Enrollment:	280
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	26-07-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-01-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL83396.018.23