Bone health in professional cycling

Published: 14-05-2020
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To examine the time course of changes BMD, bone strength and bone micro-architecture in professional cycling.

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

Summary

ID

NL-OMON52815

Source
ToetsingOnline

Brief title
Bone health and cycling

Condition

- Other condition

Synonym
Bone health, osteoporosis

Health condition

botgezondheid

Research involving
Human

Sponsors and support

Primary sponsor: Hogeschool van Arnhem en Nijmegen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bone mineral density, Cycling

Outcome measures

Primary outcome

Bone health: whole body and regional (lumbar spine and femoral hip) bone mineral density and bone mineral content as determined by dual-energy X-ray absorptiometry (DXA).

Secondary outcome

Cycling exercise volume during the preceding 12 months (for retired cyclists we obtain the average volume during a 5 year period in their career).

Dietary intake (energy, macronutrients, calcium, vitamin D)

Blood parameters of bone health: Procollagen type I N propeptide (PINP), carboxy-terminal crosslinking telopeptide of type I collagen (CTX-I), calcitonine, parathyroid hormone (PTH), testosterone oestrogen.

History of sports participation during life.

Bone microarchitecture and bone strength will be assessed by HR-pQCT. A scan takes ~2 minutes, is painless, non-invasive and involves only low radiation exposure (effective radiation dose of ~5 µSv).

Study description

Background summary

Bone health is a critical factor for athletes as bones provide the levers for muscles to move the joints, and strong bones decrease the risk of fractures during falling. Weight-bearing physical activity substantially impacts bone mineral density (BMD), while non-weight-bearing activities, such as cycling, do

not contribute to bone health. Indeed, earlier research has shown that cyclist have lower BMD than their active counterparts. However, limited data in professional cycling is available. Furthermore, there is no data available on the progression of low BMD during the active career of professional cyclists. In line, it is unknown whether the low BMD recovers after the active career of professional cyclists. Such data is warranted to assess potential health risks in this population, and to determine the necessity for interventions to prevent and counteract the loss of bone mass. In addition, high-resolution peripheral quantitative computed tomography (HR-pQCT), a relatively new imaging modality that allows detailed in vivo assessment of the cortical and trabecular compartments of peripheral bone, can be used to further the understanding of the bone mechanical properties (bone micro-architecture and bone strength) of elite cyclists.

Study objective

To examine the time course of changes BMD, bone strength and bone micro-architecture in professional cycling.

Study design

Observational study design.

Study burden and risks

Bone health will be assessed once by DXA for the present and retired cyclists and twice yearly for 4 years for the talented cyclists. The measurement is painless, non-invasive and involves only low radiation exposure. The DXA scanning includes imaging of the whole body for the determination of fat mass and fat free mass (radiation dose ~0.003 - 0.008 mSv). In addition, images of the lumbar spine (radiation dose ~0.005 - 0.014 mSv) and hip (radiation dose ~0.002 - 0.004 mSv) will be made for the assessment of bone density. The cumulative effective radiation dose will be ~0.010 - 0.026 mSv. In comparison, the daily radiation dose from natural sources in the Netherlands (cosmos, food, soil) is ~0.003, and the radiation dose from a one-way intercontinental flight is ~0.050 mSv. Thus, the radiation involved in this study is marginally higher than the daily radiation dose from natural sources, but substantially lower than an intercontinental flight.
The risks of participation in the HR-pQCT is limited to a relatively low exposure of radiation. Each HR-pQCT scan has an effective radiation dose of ~0.005 mSv, which brings the total radiation dose of study participation (i.e. HR-pQCT) to ~0.02 mSv (i.e. two radius and two tibia scans). In case motion artefacts necessitate a repeated HR-pQCT scan, a participant is exposed to a maximum radiation dose of ~0.04 mSv when all four scans have to be repeated. The cumulative effective radiation dose for a participant that undergoes both DXA and HR-pQCT will be minimal 0.03 and maximal 0.066 mSv per year.

Venous blood will be collected. For this procedure, a small needle will be inserted into the antecubital vein and blood (35 mL) will be collected through a closed system attached to the needle. The discomfort of this procedure is transient and is comparable to having an injection by a needle, or donating blood.

The time invested by participants is approximately 60-90 minutes per visit, and 30 minutes per visit for the HR-pQCT, excluding traveling time.

Taken together, the total burden en health risk by participating in this study are considered low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Male and female (18y+)
Professional cyclist competing in UCI*s WorldTour competition or a talent of that team.
Former professional cyclists (35y+)
Willing to give written informed consent.
Willing to comply with study procedures.

Exclusion criteria

Having a history of medical events or medication use that may significantly affect bone metabolism, to be decided by the principal investigator.
Medication use that may affect tests within this study must be minimal 3 months before Day 01 of this study.
Participation in any clinical trial including blood sampling and/or administration of substances up to 30 days before Day 01 of this study
A recent injury that may significantly affect BMD, to be decided by the principal investigator.
Participants who have had a traumatic fracture recently (<2 years) at either distal radii and tibiae will be excluded from the HR-pQCT measurement.
Female participants who are pregnant

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	14-05-2020
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-11-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	17-11-2022
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL72629.096.20