Bone health in professional cycling

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27586

Source
Nationaal Trial Register

Brief title
BONE

Health condition

Osteoporosis

Sponsors and support

Primary sponsor: HAN University of Applied Sciences
Source(s) of monetary or material Support: Eat2Move

Intervention

Outcome measures

Primary outcome

Whole body and regional (lumbar spine and femoral hip) bone mineral density (t- and z-scores) and bone mineral content as determined by dual-energy X-ray absorptiometry (DXA).

Secondary outcome

Whole body and regional (lumbar spine and femoral hip) bone mineral content as determined by dual-energy X-ray absorptiometry (DXA).

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 (P1NP), carboxy-terminal crosslinking telopeptide of type I collagen (CTX-I), calcitonine, parathyroid hormone (PTH), testosterone and oestrogen.
Current and life time sports participation.

Study description

Background summary

Bone is a highly dynamic tissue that undergoes constant remodeling, mainly influenced by physical activity. Non-weight-bearing activities, such as cycling do not contribute to bone health, with potentially severe consequences for individuals who engage in high volume non-weight-baring exercise training and competition such as professional cyclists. There is a lack of data on the time course and severity of low bone mineral density in professional and retired cyclists. We hypothesize that the greater part of professional cyclist will be diagnosed with osteopenia or osteoporosis. Furthermore, we expect that low bone mineral density will not be normalized after the active career.

Study objective

We hypothesize that the greater part of professional cyclist will be diagnosed with osteopenia or osteoporosis. Furthermore, we expect that low bone mineral density will not be normalized after the active career.

Study design

A subgroup of young talented cyclists will be followed over a 4 year period, including yearly measurements of bone mineral density during the off-season.

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria

World tour level (highest level) professional male cyclists (aged 22 – 40):
• Male
• Professional cyclist competing in UCI’s WorldTour competition
• Willing to give written informed consent.
• Willing to comply with study procedures.
• Accept use of all encoded data, including publication, and the confidential use and storage of all data for 15 years.

World tour level professional female cyclists (aged 22 – 40):
• Female
• Professional cyclist competing in UCI’s Women’s WorldTour competition
• Willing to give written informed consent.
• Willing to comply with study procedures.
• Accept use of all encoded data, including publication, and the confidential use and storage of all data for 15 years.

Talented elite male cyclist (aged 18 – 22):
• Male
• Included in a talent program of professional cycling team
• Willing to give written informed consent.
• Willing to comply with study procedures.
• Accept use of all encoded data, including publication, and the confidential use and storage of all data for 15 years.

Retired world tour level professional cyclists (aged 35 – 60):
• Retired male of female professional cyclist.
• A minimum of 5 years of professional cycling at WorldTour level.
• Duration of retirement is minimal 1 year before Day 01 of this study.
• Willing to give written informed consent.
• Willing to comply with study procedures.
• Accept use of all encoded data, including publication, and the confidential use and storage

of all data for 15 years.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2020
Enrollment:	75
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
Not applicable

Ethics review

Positive opinion

Date:	08-06-2020
Application type:	First submission

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
NTR-new	NL8691
Other	METC Zuyderland : METCZ20200039

Study results

Summary results
Not applicable