Bone health in professional cycling

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27586

Bron
Nationaal Trial Register

Verkorte titel
BONE

Aandoening

Osteoporosis

Ondersteuning

Primaire sponsor: HAN University of Applied Sciences
Overige ondersteuning: Eat2Move

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
Not applicable

Ethische beoordeling

Positief advies

Datum:	08-06-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8691
Ander register	METC Zuyderland : METCZ20200039

Resultaten

Samenvatting resultaten
Not applicable