ISRCTN14155111 https://doi.org/10.1186/ISRCTN14155111

Vitamin D supplementation on body composition in basketball players

Submission date
03/11/2020

Recruitment status
No longer recruiting

Registration date
06/11/2020

Overall study status
Completed

Last Edited
13/08/2021

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The main purpose of this research study is to see if taking Vitamin D supplements will improve bone health in basketball players. A previous study performed on Oakland University student-athletes showed that basketball players, especially male participants, had the lowest Vitamin D levels compared with other athletes. Thus, this study will follow-up by seeing whether or not giving Vitamin D supplements can improve the physical response to training, especially improving bone mass, and mood state in response to hard summer training.

Who can participate?
Members of Oakland University's Men's and Women's Basketball team aged between 18 and 25 years. Participants will not be eligible for this study if they have a history of fainting due to having blood drawn. Also, since the radiation exposure from dual-energy x-ray absorption (DXA) scans (used to assess body composition) can be harmful to a developing fetus (baby), participants who are pregnant or think they may be pregnant will not be allowed to participate in this study.

What does the study involve?
This study requires testing twice in the lab. At the beginning of the study, participants will come into the lab and have a teaspoon of blood drawn for analyses of vitamin D levels and then undergo a DXA scan to see how much fat, lean (muscle), and bone mass they have. Then, participants will be given a supplement (either vitamin D or a placebo pill) once a week during 12-weeks of summer strength training. After 3-months of summer training is over, they will come into the lab once more to have their blood drawn (for vitamin D levels) and a DXA scan.

What are the possible benefits and risks of participating?
The possible benefits to participants from participating in the research study are knowing their Vitamin D levels and determining if taking a Vitamin D supplement can help them (and other basketball players) build more bone mass, improving conditioning gains, and improving their mood state during the off-season training. The results of this investigation could benefit athletes, coaches, trainers, and doctors by providing evidence to support (or not) measurement

of blood Vitamin D levels throughout the season. The risks of participating include discomfort and infection from the blood draw and being exposed to small doses of radiation during the DXA scans (equal to a normal days worth of radiation exposure).

Where is the study run from?
Oakland University (USA)

When is the study starting and how long is it expected to run for?
From October 2016 to December 2019

Who is funding the study?
The study is funded by Oakland University's University Research Council (URC) Fellowship award to Tamara Hew-Butler

Who is the main contact?
Tamara Hew-Butler
tamara.hew-butler@wayne.edu

Contact information

Type(s)
Scientific

Contact name
Prof Tamara Hew-Butler

Contact details
2152 Faculty Administration Building
656 West Kirby
Detroit
United States of America
48202
+1 313-577-8130
tamara.hew-butler@wayne.edu

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Vitamin D supplementation on bone turnover in NCAA D1 collegiate basketball players: a pilot study

Study objectives
Modest (4000 IU/week) Vitamin D3 supplementation will augment bone and muscle mass in collegiate basketball players undergoing three months of strength training, over placebo supplementation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved on 24/07/2017, Oakland University's Institutional Review Board (OU IRB) (The Research Office, Wilson Hall, 371 Wilson Boulevard, Rochester, Michigan 48309-4486 +1 (248) 370-4306; kwydeven@oakland.edu), ref: 922734

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
See additional file ISRCTN14155111_PIS_24July2020 (added 02/12/2020)

Health condition(s) or problem(s) studied
Increase bone and muscle strength in collegiate basketball players

Interventions
Members from a men and women’s National Collegiate Athletic Association (NCAA) Division 1 (D1) basketball team will be recruited to participate. All subjects will give informed consent before participating in the study, which will be conducted in accordance with the Declaration of Helsinki. After obtaining written informed consent, all participants will undergo pre-intervention testing which will be conducted prior to summer strength training. Players will then be randomized (single-blind, with participants blinded to the intervention) at a ratio of 1:1 to receive either a Vitamin D (Vitamin D3, 4000IU soft gels, Up&Up™, Greenville, SC) or placebo capsule (Gelatin 1300mg Spring Valley, Bentonville, AR) weekly. The randomization order was odd/even while ensuring that a racial balance between African American and Caucasian players existed between the two supplement groups, during the randomization process.

Supplementation will occur weekly for logistical reasons as the IRB limited the daily dose to 4000IU and the investigators can only access the basketball players once per week. The dosage is based upon current recommendations (600 IU/day or 4200 mg/week with a daily tolerable upper limit of 4000 IU) for healthy young (19-50 years) individuals. Weekly supplementation will be administered by the research team over a 12-week period. Researchers will bring the supplements in (labeled) plastic cups to the weight-training room and dispense them after completion of every Monday's workout.

Intervention Type
Supplement

Primary outcome measure
Bone mass measured using whole body dual x-ray absorptiometry (DXA) scans performed at baseline and 12 weeks

Secondary outcome measures
1. Total body lean mass measured using whole body dual x-ray absorptiometry (DXA) scans performed at baseline and 12 weeks
2. Total body fat mass measured using whole body dual x-ray absorptiometry (DXA) scans performed at baseline and 12 weeks

Overall study start date
16/10/2016

Completion date
30/12/2019

Eligibility

Key inclusion criteria
1. National Collegiate Athletic Association (NCAA) Division 1 (D1) basketball players currently eligible to play for the upcoming season
2. Aged between 18 and 25 years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
23

Key exclusion criteria
1. History of fainting during blood draw
2. Pregnancy

Date of first enrolment
27/06/2017

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
United States of America

Study participating centre
Oakland University
Rochester
United States of America
48309

Sponsor information

Organisation
Wayne State University

Sponsor details
656 West Kirby
Detroit
United States of America
48202
+1 313-577-0014
aj4391@wayne.edu

Sponsor type
University/education

Website
https://wayne.edu/

ROR
https://ror.org/01070mq45

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded by Oakland University URC Summer Fellowship Award

Results and Publications

Publication and dissemination plan
We are in the process of submitting the results of this study for publication.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		24/07/2020	02/12/2020	No	Yes
Protocol file		24/07/2020	02/12/2020	No	No
Preprint results		02/03/2021	13/08/2021	No	No