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Long-term bovine colostrum supplementation in football players

Submission date
18/10/2023

Recruitment status
No longer recruiting

Registration date
07/11/2023

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Physical exercise, especially of high intensity, is a significant burden to the athlete's body. It should be emphasized that achieving high results in competitive sports requires the use of significant, sometimes extreme, exercise loads during training, which may result in homeostasis disorders, adversely affecting the fitness of athletes. The supplementation of bovine colostrum (BC) has a documented immunomodulatory effect on the players' diet and may be one of the elements of a safe and gentle intervention that restores homeostasis e.g., the balance of the immune system. There is also increasing evidence that BC may be a valuable supplement for athletes to aid exercise performance and recovery
Thus the study aims to investigate the effects of 6 months of bovine colostrum supplementation on indicators of immune system functioning, selected parameters related to iron management, pro-anti inflammatory and anabolic/catabolic balance in young football players.

Who can participate?
The research participants were men, football players who met the following criteria: the inclusion criteria included: 1) competitive football training for at least 3 years; 2) male; 3) not taking any medications throughout the study and 4) providing voluntary consent for participation in the study. The exclusion criteria included: 1) any health problems.

What does the study involve?
The study is a randomized clinical trial designed to compare the effects of 6 months of bovine colostrum supplementation on the functioning of the immune system of soccer players. A standardized stress test will be performed at the beginning of the trial and after 3 and 6 months of supplementation. Blood samples were taken before and after the stress test and after 3 hours of rest. Blood will be taken from each athlete from the ulnar vein in the amount of 2x4ml (clot test tube and EDTAK2 tube): on an empty stomach, immediately after exercise and 3 hours after exercise The level of: IGF-1, testosterone, cortisol, IL-10, IL-6, TNF-α, IgG, lactoferrin, iron, hepcidin, TIBC, UIBC will be determined. A significant increase in IgG levels was seen, accompanied by a decrease in inflammatory markers (TNF-α).

What are the possible benefits and risks of participating?
The main benefits of taking the supplement are shortening the time and improving post-

exercise regeneration processes in athletes, improving the functioning of the immune system, strengthening immunity, and regulating hormonal balance, which in intensively training athletes are disturbed by physical exercise. Previously conducted studies indicate that the dose administered in our studies is safe for humans and does not cause side effects.

Where is the study run from?
Department of Human Physiology, Nicolaus Copernicus University Ludwik Rydygier Collegium Medicum in Bydgoszcz (Poland)
Department of Biological Sciences, Faculty of Physical Culture in Gorzow Wielkopolski, Poznan University of Physical Education (Poland)

When is the study starting and how long is it expected to run for?
February 2017 to November 2018

Who is funding the study?
Regional Operational Program—Lubuskie 2020 (Poland)

Who is the main contact?
Dr Joanna Ostapiuk-Karolczuk, j.ostapiuk@awf-gorzow.edu.pl

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title
The influence of the supply of polyphenol compounds on the parameters of the pro-oxidant and pro-oxidant balance and inflammation indicators in physically active people

Acronym
LTBCSFP

Study objectives
H1. Bovine colostrum supplementation will improve iron metabolism in training soccer players in response to intense physical exercise.
H2. Bovine colostrum supplementation will improve the functioning of the immune system in training soccer players in response to intense physical exercise.
H3. Bovine colostrum supplementation will have a positive effect on the pro-anti-inflammatory balance in training football players in response to intense physical exercise.
H4. Bovine colostrum supplementation will influence the hormonal balance in training football players in response to intense physical exercise.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/06/2017, Bioethics Committee of the Nico-laus Copernicus University in Toruń at the Collegium Medicum Ludwik Rydygier (M.Skłodowskiej-Curie 9, Bydgoszcz, 85-094, Poland; +48 52 585 25 63; komisja.bioetyczna@cm.umk.pl), ref: KB 382/2017

Study design
Interventional randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Fitness/sport facility, Laboratory

Study type(s)
Prevention

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Prevention of iron, inflammatory, and hormonal disturbances in trained athletes after intense exercise.

Interventions
Before the supplementation, the players were randomly divided into two groups. The supplemented group (n=19) received four gastro-resistant capsules of BC (produced by AGRAPAK, Poland) every morning and evening. One gel capsule contained 0.4 g of colostrum. The composition of the supplement per day dose of 3.2 g of colostrum (four capsules in the morning and four in the evening): total protein - 2.620 g, lactose - 0.16 g, fat - 0.05 g, active protein substances (lactoferrin - 30 mg, PRP (platelet-rich plasma) - 0.16 g, IgG - 1050 mg, IGF - 16 µg, LZM - 21.2 mg, and αLA - 30 mg). The PRP content was estimated by measuring the content and ratio of amino acids (Pro and Val) based on the conducted research and analysis of bibliographic data. The placebo group (n=9) received powdered milk in the same dose, form, and date as the competitors. The composition of the placebo was calculated for a single dose of 3.2 g: lactose 1.6 g, protein 1.08 g, fat 0.04 g, and ash 0.25. The supplementation period lasted for 24 weeks in total.

The supplement study was performed using two types of preparations: a supplement and a placebo. Identical-looking capsules were prepared for both preparations. The contents (supplement and placebo) were very similar to each other (white powder) with virtually identical taste and smell consistency. Both preparations were packed in identical packages, marked with numbers that corresponded to the numbers assigned to the athletes during randomization. Only the study leader knew the details of the coding and he supervised the distribution of preparations for athletes. Neither the participants nor the people conducting the experiment had access to key information that could influence its course. This information is available only to the main coordinator of the experiment - the study leader, who does not participate in the experiment himself, but analyzes its results after other people have completed collecting all the data.

Intervention Type
Supplement

Primary outcome measure
Immune system activity and inflammatory response were measured using IgG level, IL-6, TNF-α, IL-10, at baseline, immediately after exercise, and 3h at each performed exercise test.

Secondary outcome measures
1. Speed of exercise measured during the Beep Test at baseline (before supplementation) and after 3 and 6 months of supplementation
2 Number of sections run in the Beep Test t baseline (before supplementation) and after 3 and 6 months of supplementation

Overall study start date
01/02/2017

Completion date
15/11/2018

Eligibility

Key inclusion criteria
1. Competitive football training for at least 3 years
2. Male

3. Not taking any medications throughout the study
4. Provide voluntary consent for participation in the study

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Days

Upper age limit
30 Days

Sex
Male

Target number of participants
Participants were assessed and randomly allocated to one of two groups: supplemented (n=19) and placebo (n=9).

Total final enrolment
28

Key exclusion criteria
Any health problems.

Date of first enrolment
07/05/2018

Date of final enrolment
10/05/2018

Locations

Countries of recruitment
Poland

Study participating centre
Department of Human Physiology, Nicolaus Copernicus University Ludwik Rydygier Collegium Medicum
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Study participating centre
Department of Physical Education; Kazimierz Wielki University
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Sponsor information

Organisation
Regional Operational Program—Lubuskie 2020

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Regional Operational Program—Lubuskie 2020

Results and Publications

Publication and dissemination plan
Results will be published in Nutrients (IF 5,9; open access)

Intention to publish date
06/11/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from (please provide contact name and email address) for 12 months from the publication date of the article. Mirosława Cieślicka e-mail: m.cieslicka@cm.umk.pl

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			19/10/2023	No	Yes
Results article		14/11/2023	21/01/2025	Yes	No