ISRCTN15330940 https://doi.org/10.1186/ISRCTN15330940

The effects of 12 weeks of bovine colostrum-enriched skim milk supplementation on immune function, antioxidant status and genomic stability in older adults

Submission date
13/07/2023

Recruitment status
No longer recruiting

Registration date
13/07/2023

Overall study status
Completed

Last Edited
05/08/2024

Condition category
Other

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

Plain English summary of protocol
Background and study aims:
Senescence is a normal biological process that is accompanied by a series of deteriorations in physiological function. As we age, our body undergoes several changes, including a gradual decline in immune function, which results in chronic low-grade inflammation. Colostrum milk, also known as "first milk," is a highly nutritious and specialized type of milk produced by mammals during the first few days after giving birth. Colostrum milk is packed with essential nutrients, including proteins, carbohydrates, and vitamins, as well as high levels of antibodies and immune factors. In addition to its immune-boosting properties, colostrum milk has been found to support gut health and improve athletic performance. Hence, this double-blinded randomized controlled trial aims to investigate the effects of bovine colostrum-enriched skim milk on the immune function, antioxidant status, genomic stability and overall health and wellbeing in older adults.

Who can participate?
Older adults aged 50 - 69 years without current or past history of cancer or undergoing chemotherapy, allergies or intolerance to dairy products, chronic kidney diseases or kidney failure, uncontrolled hypertension or diabetes, and heart or cardiovascular disease are eligible to participate in this study.

What does the study involve?
The total duration of this double blinded randomized controlled trial is 12 weeks, and the participants who meet the inclusion and exclusion criteria of the study will be randomized into treatment or placebo group according to gender using computer-generated software (SPSS).

The treatment use for this study is bovine colostrum-enriched skim milk, which contains 150 mg of IgG in each sachet (15 g) in the form of pasteurized milk powder. The treatment product is prepared by blending bovine colostrum powder with instantized skim milk powder. The IgG in the product is derived from the added bovine colostrum powder, with each sachet containing at

least 1% IgG, equivalent to approximately 150 mg per sachet. Meanwhile, the placebo for this study is regular bovine skim milk powder, without colostrum enrichment (15 g per sachet). Each participant in the treatment and placebo groups will be instructed to consume the treatment or placebo products, with two sachets to be consumed daily for 12 weeks.

The data will be collected and measured before the intervention (baseline) and after 12 weeks of intervention (post-intervention). The immunomodulatory effects, antioxidant and oxidative stress status and genomic stability enhancement effects will be by using the blood samples collected during baseline and post-intervention. Then, the changes in body mass index, waist and hip circumferences, cognitive function, physical fitness, quality of life, blood pressure and blood clinical profile (fasting blood glucose, lipid profile, liver function test, renal function test, hematology profile, vitamin D and calcium levels) will be determined by comparing the data during baseline and post-intervention.

What are the possible benefits and risks of participating?
The participants may benefit from consuming colostrum-enriched skim milk or regular milk (placebo). Apart from the potential health benefits derived from bovine colostrum, skim milk is also a rich source of various nutrients, including protein and minerals such as calcium. Additionally, participants will receive free health and clinical laboratory assessments. Since the treatment and placebo used in this study are common dairy products available in the market, the risks for participants are minimal. Furthermore, the study minimizes risk by excluding participants with critical illnesses and uncontrolled chronic diseases, as they may potentially experience complications from consuming the treatment and placebo products.

Where is the study run from?
Centre for Healthy Ageing and Wellness, Faculty of Health Sciences, Universiti Kebangsaan Malaysia.

When is the study starting and how long is it expected to run for?
November 2020 to May 2022

Who is funding the study?
1. SNI SDN. BHD. (Malaysia)
2. Universiti Kebangsaan Malaysia

Who is the main contact?
Associate Professor Dr. Razinah Sharif, razinah@ukm.edu.my

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Additional identifiers

Protocol serial number

JEP-2021-174

Study information

Scientific Title
Immunomodulatory, oxidative damage protection and genomic stability effects of bovine colostrum-enriched skim milk supplementation in older adults subjects: a randomized controlled trial

Study objectives
Colostrum-enriched skim milk can improve the immune function, protect against oxidative damage and enhance genomic stability better than the regular skim milk in older adults.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/05/2021, Research Ethics Committee, Universiti Kebangsaan Malaysia (Sekretariat Etika Penyelidikan Universiti Kebangsaan Malaysia, Tingkat 1, Blok Klinikal, Hospital Canselor Tuanku Muhriz,Pusat Perubatan UKM, Jalan Yaacob Latif, Bandar Tun Razak, Cheras, Kuala Lumpur, 56000, Malaysia; +60 391455046; sepukm@ukm.edu.my), ref: UKM PPl/111/8/JEP-2021-174

Primary study design
Interventional

Study design
Multicenter interventional double-blinded randomized controlled trial

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Promotion of healthy ageing in older adults

Interventions
The treatment use for this study is bovine colostrum-enriched skim milk, which contains 150 mg of IgG in each sachet (15 g) in the form of pasteurized milk powder. The investigational product is prepared by blending bovine colostrum powder with instantized skim milk powder. The IgG in the product is derived from the added bovine colostrum powder, with each sachet containing at least 1% IgG, equivalent to approximately 150 mg per sachet. Each participant in the intervention group will be instructed to consume the IgCo bovine colostrum-enriched skim milk, with two sachets to be consumed daily for 12 weeks.

The placebo for this study is regular bovine skim milk powder, without colostrum enrichment (15 g per sachet). Each participant in the control group will be instructed to consume the regular skim milk, with two sachets to be consumed daily for 12 weeks.

The total duration of the study is 12 weeks, and the participants who meet the inclusion and exclusion criteria of the study will be randomized into treatment or placebo group according to

gender using computer-generated software (SPSS). Data will be collected before the intervention (baseline) and after 12 weeks of intervention (post-intervention).

Intervention Type
Supplement

Primary outcome(s)
1. Immunomodulatory effects is assessed by immunophenotyping (CD markers) and mean plasma IL-6, IL-10, TNF-alpha and CRP levels at baseline and 12 weeks after intervention commencement.
2. Antioxidant and oxidative stress status is measured by mean plasma MDA levels and SOD activities at baseline and 12 weeks after intervention commencement.
3. Genomic stability is measured by mean plasma 8-OHdG and telomerase levels at baseline and 12 weeks after intervention commencement.

Key secondary outcome(s)
1. Changes in body mass index (kg/m²), waist and hip circumferences (cm) at baseline and 12 weeks after intervention commencement.
2. Cognitive function measured by MMSE, RAVLT, digit symbol and digit span tests questionnaires at baseline and 12 weeks after intervention commencement.
3. Physical fitness measured using handgrip dynamometer and timed up and go test at baseline and 12 weeks after intervention commencement.
4. Quality of life measured using WHOQOL-BREF questionnaire at baseline and 12 weeks after intervention commencement.
5. Blood pressure measured using blood pressure monitor at baseline and 12 weeks after intervention commencement.
6. Fasting blood glucose, lipid profile, liver function test, renal function test, hematology profile, vitamin D and calcium levels measured by accredited medical laboratory testing at baseline and 12 weeks after intervention commencement.

Completion date
10/05/2022

Eligibility

Key inclusion criteria
Community-dwelling older adults aged 50 - 69 years

Participant type(s)
Resident

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 Years

Upper age limit
69 Years

Sex
All

Total final enrolment
66

Key exclusion criteria
1. Current or past history of cancer or on chemotherapeutic regiment
2. Subjects allergic/intolerance to dairy products
3. Subjects with chronic kidney diseases/kidney failure
4. Subjects with uncontrolled hypertension or diabetes
5. Subjects with heart or cardiovascular disease
6. Lactating and pregnant women

Date of first enrolment
27/11/2021

Date of final enrolment
21/01/2022

Locations

Countries of recruitment
Malaysia

Study participating centre
Surau Al-Mustaqim
5, Jalan AU 5c/8, Au 5
Kuala Lumpur
Malaysia
54200

Study participating centre
Masjid Sungai Ramal Luar
Jalan Sungai Ramal
Taman Bukit Meringin
Kajang
Selangor
Malaysia
43000

Sponsor information

Organisation
SNI SDN BHD

Funder(s)

Funder type
Industry

Funder Name
SNI SDN BHD

Funder Name
Universiti Kebangsaan Malaysia

Alternative Name(s)
Universiti Kebangsaan Malaysia (UKM), Universiti Kebangsaan Malaysia (UKM), Malaysia, ukminsta, Universiti Kebangsaan Malaysia - UKM, Universiti Kebangsaan Malaysia (Malaysia), University Kebangsaan (Malaysia), UKM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Associate Professor Dr Razinah Sharif (razinah@ukm.edu.my).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/07/2023	05/08/2024	Yes	No
Participant information sheet			13/07/2023	No	Yes