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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
13/07/2023		☐ Protocol		
Registration date 13/07/2023	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
05/08/2024	Other			

### 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

### Contact information

### Type(s)

Principal investigator

### Contact name

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**Public** 

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### Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### 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

### Study design

Multicenter interventional double-blinded randomized controlled trial

### Primary study design

Interventional

### 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  $(kg/m^2)$ , 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-Mustagim

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

### 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes