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A randomized placebo-controlled trial for evaluating effects of consumption of perilla fruit (Nga-keemon) oil-added soybean milk on health outcomes and blood biomarkers among healthy subjects

Submission date	**Recruitment status**	[_] Prospectively registered
19/03/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/03/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/05/2023	Other	

Plain English summary of protocol

Background and study aims
Perilla fruit oil (PFO) is rich in omega 3-polyunsaturated fatty acids, particularly alpha-linolenic acid, which has been noted for its numerous health benefits. Functional foods are cornerstone strategies in sustaining wellness in humans. This study aims to develop PFO-fortified soybean milk (PFO-SM), identify its degree of sensory acceptability, and evaluate the relevant health outcomes. This study assesses the effects of the consumption of perilla fruit oil-fortified soybean milk and black sesamin-fortified soybean milk in healthy volunteers.

Who can participate?
Healthy male and female volunteers aged 20-60 years

What does the study involve?
Participants are randomly allocated into four groups. Group 1 is given deionized water (DI), Group 2 is given soybean milk (SM), Group 3 is given perilla fruit oil-fortified soybean milk (PFO-SM), and Group 4 is given black sesamin-fortified soybean milk (BS-SM). Participants consume the drink (a 180 ml serving) after meals twice daily for 30 days.

What are the possible benefits and risks of participating?
In terms of the potential benefits, the participants will find out about their relevant health outcomes, the levels of blood biochemical biomarkers and antioxidant capacities, and applicable immune functions after consumption of the pasteurized PFO-SM drink when compared to the SM and BS-SM drinks. Participants are not expected to suffer any adverse effects nor experience any food allergies related to the consumption of the drinks according to the exclusion criteria. However, the participants may feel slightly uncomfortable or experience very minor levels of pain when blood samples are being collected.

Where is the study run from?
Chiang Mai University (Thailand)

When is the study starting and how long is it expected to run for?
January 2015 to April 2015

Who is funding the study?
1. Agricultural Research Development Agency of Thailand (Thailand)
2. Chiang Mai University (Thailand)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
Research ID: 2829, Study code No. FAM-2558-02829

Study information

Scientific Title
Perilla frutescens var. keemon fruit oil-fortified soybean milk intake alters levels of serum triglycerides and antioxidant status, and influences phagocytotic activity among healthy subjects

Study objectives
It is hypothesized that Perilla frutescens fruit oil (PFO) which is rich in omega 3-polyunsaturated fatty acids, particularly alpha-linolenic acid (ALA), would be fortified in soybean milk (SM) for production of functional pasteurized PFO-SM drink. The drink would be beneficial for human by

improving health indices, hematological parameters and blood biochemical biomarkers, resulting in better quality of life and longevity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/01/2015, the Institutional Review Board (Set 4) of Faculty of Medicine, Chiang Mai University (110 Intawaroros Street, Sriphum, Muang Chiang Mai 50200, Thailand; +66 (0)53 936209 Ext 22; researchmed@cmu.ac.th), ref: 2829/study code no. FAM-2558-02829

Primary study design
Interventional

Study design
Single-center randomized controlled demonstration trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Comparative effects on consumption of perilla fruit oil-fortified soybean milk and black sesamin-fortified soybean milk in healthy adult subjects

Interventions
In this clinical trial, the block randomization method was employed in order to randomise healthy subjects (n = 192, male and female) who were then divided into four groups (n = 48 each): Group 1 was given deionized water (DI), Group 2 was given soybean milk (SM), Group 3 was given perilla fruit oil-fortified soybean milk (PFO-SM), and Group 4 was given black sesamin-fortified soybean milk (BS-SM). Herein, the above-mentioned method was employed to ensure a balance in the sample size across all groups over time. Accordingly, the subjects in groups 2, 3, and 4 were assigned to consume the drink (180 ml serving) after meals twice daily for 30 days.

All statistical analyses were performed using the SPSS Program version 18.0 (IBM, NY, USA licensed by Chiang Mai University) and expressed as values of mean ± standard deviation (SD). When all variables were not distributed normally (Kolmogorov–Smirnov test), nonparametric analysis was performed. Differences observed at different times within the same group were analyzed with the parametric paired samples obtained from the paired Student's t-test or the non-parametric Wilcoxon test. Any differences observed between the two groups were analyzed using the parametric independent samples of the t-test or the non-parametric Mann-Whitney U test. The differences between the three groups were analyzed using the parametric analysis of variance (ANOVA), followed by post hoc Tukey's HSD, Dunnett T3, or the non-parametric Kruskal-Wallis test. Accordingly, p values of < 0.05 were considered statistically significant, as were ap values of < 0.05 when compared with the baseline (D0) in the same group using a parametric paired Student's t-test; bp values of < 0.05 when compared with the baseline (D0) in the same group using non-parametric Wilcoxon test; cp values of < 0.05 when compared between changes of three groups in the brackets using parametric one-way ANOVA followed by post hoc Tukey's HSD or Dunnett T3 tests; and dp values of < 0.05 when comparisons were made between changes of the 3 groups in the brackets using non-parametric Kruskal-Wallis test.

Intervention Type

Supplement

Primary outcome(s)
1. Systolic/diastolic blood pressure measured using an aneroid sphygmomanometer with a cuff at the baseline (day 0) and at the end of the study (day 30)
2. Hematological parameters measured using an automated cell counter/analyzer (Beckman Coulter Life Sciences, Indianapolis, NJ, USA) according to the manufacturer's instructions on days 0 and 30
3. Blood biochemical parameters, including blood urea nitrogen (BUN), creatinine (CRE), aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), total cholesterol (TC), triglycerides (TG), high-density lipoprotein-cholesterol (HDL-C), and low-density lipoprotein-cholesterol (LDL-C), analyzed using an automated clinical chemistry analyzer (Randox Laboratories Limited, County Antrim, UK) according to the manufacturer's instructions on days 0 and 30
4. Phagocytotic activity in the blood measured according to established methods on days 0 and 30
5. ROS in RBC detected using the dichlorofluorescein diacetate/flow cytometry method on days 0 and 30
6. Serum thiobarbituric acid-reactive substance (TBARS) concentrations measured using the colorimetric method on days 0 and 30
7. Superoxide dismutase (SOD) activity determined using Dojindo's highly water-soluble tetrazolium salt with WST-1 as an electron acceptor according to the procedure described by the manufacturer on days 0 and 30
8. Serum reduced glutathione (GSH) concentration determined based on the non-enzymatic reduction of 5,5'-dithiobis(2-nitrobenzoic acid) substrate to yellow-colored 5-thio-2-nitrobenzoic acid product on days 0 and 30
9. Total antioxidant capacity (TAC) value in the serum measured using 2,2-diphenyl-1-picryl-hydrazyl (DPPH) radical scavenging assay on days 0 and 30

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
10/04/2015

Eligibility

Key inclusion criteria
1. Not allergic to soybeans or perilla nutlets
2. Not currently participating in any vitamin, supplementary food, or any other controlled diet programs
3. Aged 20-60 years old

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
196

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
10/02/2015

Date of final enrolment
10/03/2015

Locations

Countries of recruitment
Thailand

Study participating centre
Chiang Mai University
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Faculty of Medicine
110 Intawaroros Street
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50200

Sponsor information

Organisation
Agricultural Research Development Agency of Thailand

Organisation
Chiang Mai University

ROR
https://ror.org/05m2fqn25

Funder(s)

Funder type
Government

Funder Name
Agricultural Research Development Agency

Alternative Name(s)
ARDA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Thailand

Funder Name
Chiang Mai University

Alternative Name(s)
Chiang Mai University, THAILAND, , , , CMU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Thailand

Results and Publications

Individual participant data (IPD) sharing plan
If access to the datasets and the data itself is needed, Dr Winthana Kusirin, PhD., RN (Midwifery) can be contacted at wkusiris@gmail.com. The data will become available from 01/04/2022 and remain available until 31/03/2027. All data will also be accessible in the supplementary files and will be shared with Dr Winthana Kusirisin.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/04/2022	22/05/2023	Yes	No