

Comparison of milk containing A1A2 beta casein and milk containing A2A2 beta casein among students of the Faculty of Public Health, Universitas Indonesia

Submission date 24/05/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/05/2018	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The symptoms of digestive discomfort after consuming dairy products are the main reasons for somebody to avoid commercial dairy products. Most suspect that post-dairy digestive discomfort is caused by lactose intolerance, but in fact some cases are because of a reaction to several types of milk proteins. Cow's milk contains two types of beta casein, A1 beta casein and A2 beta casein. The A1 beta casein type commonly found in commercial milk is broken down into beta-casomorphin-7 (BCM-7) in the digestive system and causes digestive discomfort. In contrast to A1 beta casein type, A2 beta casein type does not produce BCM-7 so it does not show similar symptoms. The aim of this study is to compare the effects of milk with different types of beta casein - i.e. milk containing beta casein combination A1 type and A2 type (A1A2 beta casein) and milk containing only A2 beta casein type (A2A2 beta casein) - on the symptoms of post-dairy digestive discomfort, stool frequency and consistency and also immune response.

Who can participate?

Undergraduate students of Faculty of Public Health, Universitas Indonesia, aged 17-25, who have symptoms of digestive discomfort after consuming dairy or cow's milk products

What does the study involve?

Participants are assessed regarding symptoms of post-dairy digestive discomfort, diet, nutritional status and blood pressure. All participants receive both milk containing A1A2 beta casein and milk containing A2A2 beta casein. They are randomly allocated to receive the milk containing A1A1 beta casein then milk containing A2A2 beta casein (sequence 1) or milk containing A2A2 beta casein then milk containing A1A2 beta casein (sequence 2). Each participant consumes two bottles of 200 ml of milk daily for 2 weeks. Both types of milk are provided by ABC KOGEN. To ensure that the sample is actually consumed by participants, they have to consume the milk at the Center for Nutrition and Health room on weekdays and at weekdays the milk is taken home by the participants then they return the used bottle. There is a two-week break between consuming the two types of milk where the participants are not

allowed to consume cow's milk products in order to remove or clear the effects of the previous milk. Participants fill out two weekdays and one weekend food diary to monitor their diet. Participants are also given a list of foods as a substitute for the source of nutrition from dairy products. Participants fill out forms about the symptoms of post-dairy digestive discomfort and stool frequency and consistency, and provide blood samples before and after the intervention to measure their immune response.

What are the possible benefits and risks of participating?

Participants will get some benefit such as knowing their body's immune response to dairy products. Overall data collection has no risks. However, an error of the screening procedure may occur so that poses a risk to this research. To minimize the risk, all data are collected by trained personnel according to the standard procedures. In addition, all of the participants are insured and receive treatment if there are any health complaints during this study.

Where is the study run from?

Universitas Indonesia

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

August 2017 to April 2018

Who is funding the study?

ABC Kogen

Who is the main contact?

Dr Ahmad Syafiq

Contact information

Type(s)

Scientific

Contact name

Dr Ahmad Syafiq

Contact details

Room 204, F Building, 2nd floor

Faculty of Public Health

Universitas Indonesia

Depok, West Java

Indonesia

16424

Additional identifiers

Protocol serial number

No.021/SP/AKD/2017

Study information

Scientific Title

Comparison of milk containing A1A2 beta casein and milk containing A2A2 beta casein to the symptoms of post dairy digestive discomfort and milk-specific IgE among students of the Faculty of Public Health, Universitas Indonesia Depok (a double-blind randomized two-way cross-over study)

Study objectives

Milk containing A2A2 beta casein decreases the symptoms of post-dairy digestive discomfort and improves immune response more than milk containing A1A2 beta casein.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Committee of Ethics Research and Public Health Service, Faculty of Public Health, Universitas Indonesia, 13/10/2017, ref: 529/UN2.F10/PPM.00.02/2017

Study design

Interventional double-blind randomized two-way cross-over single-centre study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Post-dairy digestive discomfort

Interventions

All participants selected in this study received two interventions, that is milk containing A1A2 beta casein and milk containing A2A2 beta casein. Participants were randomized to decide who received the milk containing A1A2 then milk containing A2A2 (sequence 1) or milk containing A2A2 then milk containing A1A2 beta casein (sequence 2). Each participant consumed 200 ml milk twice a day for 2 weeks of intervention. Both types of milk were provided by ABC KOGEN. Before entering second intervention, there are a washout period (intervention-free). In this period, the participants will not get any intervention for 2 weeks to remove or clear the effects of previous intervention. The participants were not allowed to consume dairy products on the washout period during this study. Participants will be given a list of foods as a substitute for the sources of nutrition from dairy products. On intervention period, participants were asked to fill out the form of symptoms of post-dairy digestive discomfort and Bristol Stool Scale as well as taking blood samples. Blood samples were taken within a range of 12 hours before or after the intervention.

Intervention Type

Other

Primary outcome(s)

1. Symptoms of post-dairy digestive discomfort, measured by questionnaire that asked the participants how they felt after milk consumption, such as bloating, abdominal pain, flatulence, heavy stomach and borborygmi (stomach rumbling). The participants were asked to fill out each questionnaire after milk consumption (twice a day) during the intervention period. Each

symptom was ranked on Likert scale, as never (score =0), rarely (score=1), moderate (score=2) and severe (score=3)

2. Immune response (milk-specific IgE antibodies), assessed by milk-specific IgE blood serum test. Blood serum sample was performed by the laboratory assistant as follows: blood samples were taken within a range of 12 hours before starting the intervention and after the intervention; laboratory assistant takes 5 ml of venous blood; samples were analyzed by ELISA (enzyme-linked immunosorbent assay) technique in the laboratory

Key secondary outcome(s)

Stool consistency and frequency, measured using The Bristol Stool Scale every day during the intervention. Stool consistency was rated on 7 type Likert scale:

Type 1: Separate hard lumps, like nuts (hard to pass)

Type 2: Sausage-shaped but lumpy

Type 3: Like a sausage but with cracks on its surface

Type 4: like a sausage or snake, smooth and soft

Type 5: Soft blobs with clear-cut edges (passed easily)

Type 6: Fluffy pieces with ragged edges, a mushy stool

Type 7: Watery, no solid pieces, entirely liquid

Completion date

19/04/2018

Eligibility

Key inclusion criteria

1. Students of Faculty of Public Health, Universitas Indonesia
2. Male or female, aged 17-25 years
3. Irregular milk consumption (FFQ screening)
4. Felt the symptoms of digestive discomfort after consume commercial dairy products
5. Have a normal blood pressure
6. BMI 19-27.5 kg/m²
7. Willing to follow all of the requirements and procedures of this study and agree to sign informed consent

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Woman in pregnancy and breastfeeding
2. Consume anti inflammatory or immunosuppressive drugs within 4 weeks before screening
3. Have an allergy

Date of first enrolment

20/10/2017

Date of final enrolment

09/12/2017

Locations

Countries of recruitment

Indonesia

Study participating centre**Universitas Indonesia**

Centers for Nutrition and Health

Faculty of Public Health

Room 204, F Building, 2nd floor

Depok, West Java

Indonesia

16424

Sponsor information

Organisation

Universitas Indonesia

ROR

<https://ror.org/03xqzzq44>

Funder(s)

Funder type

Industry

Funder Name

ABC Kogen

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary

Not expected to be made available