Impact of A2 milk versus conventional milk on intestinal health: a proof-of-concept study in Irritable Bowel Syndrome patients

Published: 11-08-2020
Last updated: 11-07-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON52571

Source
ToetsingOnline

Brief title
A2 Milk Proof-of-concept

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Irritable Bowel Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Afdeling Maag-;Darm-;Leverziekten (MUMC+) ,Organic A2 Dairy

Intervention

Keyword: Gastrointestinal symptoms, Immune system, Irritable Bowel Syndrome, Milk

Outcome measures

Primary outcome

Overall GI discomfort

Secondary outcome

Single GI symptoms

Stool characteristics (frequency and consistency)

BCM-7 in blood

Effect of baseline characteristics on objectives

Study description

Background summary

Dairy products such as cow*s milk are widely produced and an important component of the human diet. Beta-casein is a major protein component of cow*s milk, includes A1 and/or A2 β-casein, and is composed of important amino acids that contribute to functions such as muscle growth. Most cows produce a mixture of A1 and A2 β-casein (conventional milk), whereas some cows produce only A2 β-casein (A2 milk). By differences in one specific amino acid at position 67 being histidine or proline, respectively, it is suggested that A2 milk will induce less gastrointestinal (GI) symptoms compared with conventional milk. Previous studies in China, Australia and New Zealand indeed showed this indeed lower GI symptoms after A2 milk vs conventional milk intake in healthy indivuals. However, further studies are needed on the comparison between A2 milk and conventional milk on prevalent GI symptoms in various geographical populations, and especially in relevant subgroups, such as irritable bowel syndrome (IBS) patients. In Western populations, IBS is a prevalent (i.e. 10%) functional bowel disorder characterized by abdominal pain and altered bowel habits. According to the Rome IV criteria, IBS subtypes include IBS with constipation (IBS-C), IBS with diarrhea (IBS-D) and mixed IBS with both

constipation and diarrhea (IBS-M). Although the pathophysiology is incompletely understood, it is generally regarded as a multifactorial disorder involving host factors such as low-grade immune activation and defense. Diet has also suggested to play a role in inducing GI symptoms in IBS patients. Therefore we aim to study GI symptoms in IBS-C and IBS-D patients.

Study objective

This study will be done to gain insights in the effects of A2 milk on GI symptoms, and immune and defense parameters, in IBS patients. The information will gain more insights in the working mechanism of different types of beta-casein in individuals which indicate that nutritional components trigger GI symptoms. In case study results will be positive, this may lead to the development of new food products such as A2 milk, to improve intestinal health.

Study design

The study conforms to a randomized, double-blind and placebo-controlled design including two cross-over intervention periods

Intervention

One 1-day intervention period subjects will ingest 200 mL A2 milk two times that day. In the other 1-day period intervention period, subjects will ingest 200 mL conventional milk two times that day. Which product will be ingested in which period (first or second) will be determined by randomization.

Study burden and risks

There are small burdens volunteers can experience during this study. After screening, participants will have to visit the Maastricht Universitair Medisch Centrum+ two times. In total, a participant will spend approximately eighteen hours at the university facility. They will have to take A2 milk or conventional milk two times during two 1-day intervention days; the products used have been proven to be safe for human use. During two visits and spread over 19 days, a total of 28 mL blood will be sampled by venepuncture via an evacuated tube system, which may lead to minor discomfort and/or a small hematoma at the site of puncture. During the both intervention days, body weight will be determined and subjects will bring a fecal sample to each intervention day which is collected at home. Moreover, daily questionnaires will have to be filled out at several occasions during this study. Besides we ask subjects to fill out a three-day food diary two times.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age between 18-70 years
Based on Rome IV criteria, IBS-C or IBS-D predominant
Indication that dietary components trigger GI symptoms

Exclusion criteria

Abdominal surgery interfering with gastrointestinal function
Lactose intolerance
Cow's milk allergy
Use of antibiotics in the 90 days prior to the study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	11-08-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-01-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-03-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04598529
CCMO	NL73898.068.20

Study results

Date completed: 05-06-2023

Summary results
Trial ended prematurely