Effect of milk containing Lactium on subjective sleep parameters.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26292

Source
Nationaal Trial Register

Brief title
"slaap-onderzoek" (sleep study)

Health condition

Mild Sleeping Disorders

Sponsors and support

Primary sponsor: Friesland Foods Western Europe, Ede, the Netherlands
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Sleep quality (assesed with the "Groningen Sleep Questionnaire") and sleep quantity.

Secondary outcome

Quality of Life en Sleepiness.

Study description

Background summary

Effect of milk containing Lactium®
on subjective sleep parameters.

Introduction:

The quality of sleep is intrinsically linked to quality of life. According to CBS thirty eight percent of the middle-aged women in the study (> 45 y) responded ‘yes’ to the question ‘Have you had sleeping problems in the past 14 days?’ Lactium® is a protein hydrolysate derived from enzymatic treatment of milk (á-S1) casein and has prooven anti-stress effects.

Objective:

The objective of the study is to study the effects of milk containing Lactium® on sleep in 200 adults with minor sleeping problems.

Methods:

The study design is a randomized, placebo controlled, double blind intervention study, with parallel groups. A total of 200 subjects will be randomised to one of the two treatments: reference (normal semi-skimmed) milk and semi-skimmed milk with Lactium. Each subject will use the study milk during 2 weeks, half-an-hour before going to sleep.

Primary outcome measures:

Daily questionnaires: Sleepiness (Scored by the Stanford Sleeping Scale in the evening), Sleep quality (Scored by the Groningen Sleep Questionnaire in the morning) and Sleep quantity (Scored in the morning).

Study objective

Milk containing Lactium significantly increases duration and quality of sleep in persons with mild sleeping disorders.

Study design

N/A

Intervention

Semi-skimmed milk with Lactium compared to semi-skimmed milk without Lactium.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy adults 20-60 years of age;

2. With regular and normal Dutch eating habits (consuming mostly three main meals including breakfast) and;

3. A regular lifestyle;

4. With sleeping problems present during more than 1 month prior to the start of the study and during 3 or more nights a week;

5. Having given their written informed consent;

6. Willing to comply with the study procedures;

7. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years;

8. Sleeping problems are defined as more than 30 minutes awake after lights out or more than 3 times awake at night or during more than 45 min awake at night.

Exclusion criteria

1. Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before the start of this study;

2. Participation in any non-invasive clinical trial up to 30 days before the start of this study, including no blood sampling and/or oral, intravenous, inhalatory administration of substances;

3. Mental status that is incompatible with the proper conduct of the study;

4. Intended vacation in the study period;

5. Having a history of medical or surgical events that may significantly affect the study outcome;

6. Use of medication for sleeping problems within three months prior to the study, and during the study;

7. Alcohol consumption > 21 units/week;

8. Frequent intense sport practice (more than 10 hours a week);

9. Reported participation on night shift work;

10. Pregnant or lactating or wishing to became pregnant in the period of the study;

11. Not having a general practitioner;

12. Not willing to accept information-transfer concerning participation in the study, or information regarding her health, like findings at anamnesis and eventual adverse events to and from her general practitioner;

13. Depression, restless legs, sleep apnoea syndrome.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2007
Enrollment:	200
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL804
NTR-old	NTR817

Register	ID
Other	: N/A
ISRCTN	ISRCTN42343515

Study results

Summary results
N/A