Effect of milk containing Lactium on subjective sleep parameters.

Gepubliceerd: 26-10-2006 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26292

Bron
NTR

Verkorte titel
"slaap-onderzoek" (sleep study)

Aandoening

Mild Sleeping Disorders

Ondersteuning

Primaire sponsor: Friesland Foods Western Europe, Ede, the Netherlands
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2007
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL804
NTR-old	NTR817
Ander register	: N/A
ISRCTN	ISRCTN42343515

Resultaten

Samenvatting resultaten
N/A