

Effect of milk containing lactium on subjective sleep parameters

Submission date 28/12/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/12/2006	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Astrid Bakker-Zierikzee

Contact details
Friesland Foods
P.O. Box 159
Ede
Netherlands
6710 BD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym

"slaap-onderzoek" (sleep study)

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised, placebo controlled, parallel group, double blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Sleep Disorders

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Lactium

Primary outcome measure

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

Secondary outcome measures

Quality of Life and Sleepiness.

Overall study start date

01/01/2007

Completion date

01/04/2007

Eligibility

Key inclusion criteria

1. Healthy adults 20 to 60 years of age
2. With regular and normal Dutch eating habits (consuming mostly three main meals including breakfast)
3. A regular lifestyle
4. With sleeping problems present during more than one month prior to the start of the study and during three 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 three times awake at night or during more than 45 minutes awake at night

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

200

Key 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 more than 21 units/week
8. Frequent intense sport practice (more than ten hours a week)
9. Reported participation on night shift work

- 10. Pregnant or lactating or wishing to become 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

Date of first enrolment

01/01/2007

Date of final enrolment

01/04/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Friesland Foods

Ede

Netherlands

6710 BD

Sponsor information

Organisation

Friesland Foods (The Netherlands)

Sponsor details

P.O. Box 159

Ede

Netherlands

6710 BD

Sponsor type

Industry

Website

<http://www.fcdf.com/>

ROR

<https://ror.org/025mtxh67>

Funder(s)

Funder type

Industry

Funder Name

Friesland Foods (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration