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Effect of milk containing lactium on subjective sleep parameters

Submission date	Recruitment status	[X] Prospectively registered
28/12/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/12/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/12/2006	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 (assesed 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 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

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