

# Effect of milk containing lactium on subjective sleep parameters

<b>Submission date</b> 28/12/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/12/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 29/12/2006	<b>Condition category</b> 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**  
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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 (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