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A study to evaluate the effect of ETAZEO supplementation on sleep quality

Submission date
18/06/2024

Recruitment status
No longer recruiting

Registration date
27/06/2024

Overall study status
Completed

Last Edited
20/06/2024

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
The health impact of improved sleep and reduced snoring cannot be underestimated. Chronic sleeplessness and other related sleep disorders have been associated with an increased risk of developing various health conditions such as hypertension, coronary artery disease, and stroke. This scientific research study is designed to test the impact of ETAZEO®, a supplement containing fermented Salvia Officinalis (sage) metabolites, on sleep and snoring in Asian participants over 4 weeks.

Who can participate?
Healthy non-smoker Asian subjects aged between 25 and 65 years old (inclusive) with the presence of chronically disturbed sleep (PSQI >5)

What does the study involve?
Participants will be randomly assigned to a once-daily ETAZEO® supplement or a placebo /dummy supplement for 4 weeks.

What are the possible benefits and risks of participating:
Possible benefits are an improvement in skin health. No risks are expected.

Where is the study run from?
INNOVATION LABO Sciences Co., Ltd (Japan)

When is the study starting and how long is it expected to run for?
June 2023 to July 2023

Who is funding the study?
INNOVATION LABO Sciences Co., Ltd (Japan)

Who is the main contact?
Dr Yuki Ikeda, development@innovationlabo.com (Japan)

Contact information

Type(s)
Scientific

Contact name
Dr Yuki Ikeda

ORCID ID
http://orcid.org/0000-0001-6067-4574

Contact details
Shintomi HJ bldg 5F
1-12-7 Shintomi
Tokyo
Japan
104-0041
+81 335525335
development@innovationlabo.com

Type(s)
Principal Investigator

Contact name
Dr Olivier Le Moal

Contact details
1 place marie Curie
Annecy
France
74000
+33 (0)4 50 33 08 63
innovation@mayor-invivo.com

Type(s)
Public

Contact name
Mrs Celine Klotz

Contact details
Shintomi HJ bldg 5F
1-12-7 Shintomi
Tokyo
Japan
104-0041
+81 335525335
tokyo@innovationlabo.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SL/IL 22-0456

Study information

Scientific Title
Double-blind placebo-controlled clinical study to evaluate the effect of supplementation with ETAZEO during 4 weeks in improving sleep quality in healthy Asian adults suffering from insomnia

Study objectives
ETAZEO is more efficient than a placebo in improving sleep quality

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/11/2022, Japanese Society of Anti-Aging Nutrition (JAAN) (Ginza, Chuo-ku, Tokyo, 104-0061, Japan; +81 3 3552 5277; coordinator@jaan.jp), ref: ILOS22633-K148

Study design
Interventional double-blind placebo-controlled single-center randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Improvement of sleep quality in participants with insomnia

Interventions

This study investigates 4 weeks of daily supplementation with ETAZEO (250 mg capsule) or a placebo (dextrin, 250 mg capsule) taken orally in the evening before sleep. Block randomization was used to allocate participants to each group.

Block randomization is used to divide potential patients into m blocks of size 2n, randomize each block such that n patients are allocated to A and n to B then choose the blocks randomly. This method ensures equal treatment allocation within each block if the complete block is used.

Intervention Type
Supplement

Primary outcome measure
Change in sleep score measured using the Pittsburgh Sleep Quality Index (PSQI) questionnaire at baseline and week 4

Secondary outcome measures
Change in snoring score measured using the Snoring Severity Scale (SSS) questionnaire at baseline and week 4

Overall study start date
12/05/2022

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Healthy non-smoker Asian male and female subjects between 25-65 years old (inclusive)
2. Presence of chronic disturbed sleep (PSQI >5)
3. Presence of chronic snoring. A patient is considered a chronic snorer if his/her bedmate /roommate reported snoring more than 5 days per week and if this is corroborated by medical analysis performed in the patient's own home. The result of the respiratory polygraphy should indicate the presence of snoring during at least 30% of the nocturnal period.
4. Have a regular roommate or bedmate to submit information
5. Subjects available during the whole period of study (1 month)

Participant type(s)
Patient

Age group
Adult

Lower age limit
25 Years

Upper age limit
65 Years

Sex

Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Subjects with sleep apnoea
2. High-risk professions and/or controlling dangerous machines
3. Moderate or severe somnolence during day time
4. Coronary cardiopathy, acute vascular disease (less than three months), chronic and severe obstructive pulmonary disease, and chronic treatment with theophyllines
5. Temporo-mandibular joint problems or periodontitis
6. Mandibular protrusion capacity less than 6 mm and/or less than 10 teeth in each jaw
7. Severe cognitive disorders and/or patients whose answers to the questionnaires will be altered by chronic and severe diseases
8. Pregnancy (since the third month of pregnancy to 3 months after birth delivery)
9. Patients on prolonged medication(more than 6 weeks) with sleep medication, corticosteroids, antidepressants, anticholinergics, antipsychotic drugs, etc. or any other drugs that may have an influence on the outcome of the study
10. Pregnant/lactating women
11. Subjects who cannot agree to refrain from alcohol consumption during the study period
12. Alcoholics and/or drug abusers
13. Subjects having history of psychiatric disorders that may impair the ability to provide written informed consent
14. Patients who have completed participation in any other clinical trials during the past 3 months
15. Any other conditions that the Principal Investigator thinks may jeopardize the study outcomes

Date of first enrolment
21/02/2023

Date of final enrolment
13/04/2023

Locations

Countries of recruitment
France

Study participating centre
Mayor In-vivo
1, place Marie Curie
Annecy
France
74000

Sponsor information

Organisation
INNOVATION LABO Sciences Co., Ltd

Sponsor details
Shintomi HJ bldg 5F, 1-12-7 Shintomi
Tokyo
Japan
104-0041 Chuo-ku
+81 (0)3-35525335
technologies@innovationlabo.com

Sponsor type
Industry

Website
https://www.innovationlabo.com

Funder(s)

Funder type
Industry

Funder Name
INNOVATION LABO Sciences Co., Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Yuki Ikeda, development@innovationlabo.com. Anonymised IPD will be available upon publication of results and for a period of 2 years. Consent from participants was required and obtained.

IPD sharing plan summary

Available on request