

The efficacy of nutraceuticals in the treatment of chronic insomnia

Submission date 18/07/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/07/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/07/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Sleep disorders and anxiety disorders, in addition to constituting a complex syndrome, represent a clinical condition in which various interconnected pathophysiological mechanisms contribute to determining the clinical phenotype.

Therefore, the ideal drug in these patients, in addition to having an anxiolytic and hypno-inducing action, should have a modulatory action on chronic stress, mood, inflammatory state, with a therapeutic action also on the cognitive and physical dimensions of the clinical syndrome. A natural supplement dedicated to a population of patients suffering from sleep disorders associated with specific and non-specific states of anxiety might be made up of 4 distinct therapeutic principles (plant extracts, amino acids, vitamins, minerals) with a strengthening action on the physiological mechanisms responsible for regulating the sleep-wake rhythm and the homeostasis of the neurotransmitter and immune systems involved in the regulation of the state of alertness, mood and the hypothalamic-pituitary-adrenal axis.

The therapeutic rationale is based on the principle of the synergy of action exerted by constituents, such as plant extracts, capable of exerting a direct action on the GABA-A receptors implicated in the induction of sleep and on the mechanisms of chronic inflammation; the precursor amino acids for the synthesis of substances such as GABA, melatonin, dopamine and serotonin; vitamins, enzymatic catalysts for the synthesis of molecules involved in the regulation of the circadian rhythm and mood states; minerals, essential as cofactors for the correct functioning of neurotransmitters, neuro-hormones, and the chemical reactions connected to them. The main objective of this prospective, observational, open-label study, lasting eight weeks, was to evaluate the efficacy and safety of a phytotherapeutic and nutraceutical compound in a sample of patients suffering from insomnia disorder associated with states of anxiety.

Who can participate?

Patients suffering from insomnia disorder according to the DSM-V criteria, associated with a state of anxiety measured according to STAI-Y1/Y2.

What does the study involve?

All participants received the same sachet of powdered herbal mixture, vitamins, essential amino acids and trace elements to be taken one per day one hour before falling asleep

What are the possible benefits and risks of participating?

The pharmacological properties of the compound under study and the related benefits, would be to reduce the state of hypervigilance and consequently, improve the quantity and quality of sleep. No concerns about the safety profile of the study compound, were anticipated

Where is the study run from?

Sapienza University of Rome (Italy)

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

April 2018 to October 2022

Who is funding the study?

Ecupharma S.r.l. (Italy)

Who is the main contact?

Dr Gianluca Bruti, gianluca.bruti@gmail.com

Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

0000698

Study information

Scientific Title

A combination of herbs, vitamins, trace elements and essential amino acids in the treatment of patients with insomnia disorder associated with anxiety symptoms: an observational, pilot, open-label, prospective, eight-week study

Study objectives

To evaluate the efficacy and safety of a nutraceutical compound composed of a combination of herbs, vitamins, trace elements and essential amino acids in the treatment of patients with chronic insomnia associated with anxiety.

Ethics approval required

Ethics approval not required

Ethics approval(s)

This study was performed in a private office and did not require any institutional regulation.

Study design

Observational prospective open-label

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Treatment of patients suffering from chronic insomnia and anxiety states.

Interventions

The study was conducted on a clinical sample of 28 patients suffering from insomnia disorder according to the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V), associated with a state of anxiety. The sample study was clinically evaluated at baseline (T0), and after four (T1) and eight weeks (T2) of phytotherapeutic and nutraceutical treatment. There was no further systematic follow-up after the eight-week study

Intervention Type

Other

Primary outcome measure

Measured at baseline and week four:

1. The Pittsburgh Sleep Quality Index (PSQI)
2. STAI-Y1 (anxiety)

Secondary outcome measures

1. PSQI at baseline and eight weeks
2. STAI-Y2 at baseline and eight weeks
3. Beck Depression Inventory (BDI) at four and eight weeks
4. Fatigue Severity Scale (FSS) at four and eight weeks
5. Depression and Anxiety Scale Short form – 21 (DASS-21) at four and eight weeks
6. Patient global impression of improvement - severity (PGI-S) at four and eight weeks
7. Rapid Stress Assessment (RSA) at four and eight weeks
8. Insomnia Severity Index at four and eight weeks
9. General health (SF-36) at four and eight weeks

Overall study start date

21/04/2018

Completion date

25/10/2022

Eligibility

Key inclusion criteria

Patients suffering from chronic insomnia according to the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders and the third edition of the International Classification of Sleep Disorders (DSM-V), associated with a state of anxiety.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

30

Total final enrolment

28

Key exclusion criteria

1. Major depressive disorders
2. Substance abuse disorders
3. Pregnancy
4. Unstable clinical status

Date of first enrolment

23/09/2021

Date of final enrolment

20/09/2022

Locations

Countries of recruitment

Italy

Study participating centre

EurekAcademy

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Sponsor information

Organisation

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University/education

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Funder(s)

Funder type

Industry

Funder Name

Ecupharma S.r.l.

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

Gianluca Bruti; gianluca.bruti@gmail.com

IPD sharing plan summary

Available on request