ISRCTN13394796 https://doi.org/10.1186/ISRCTN13394796

A study to investigate the safety and efficacy of Maizinol™ on sleep quality in a healthy population with difficulty falling asleep or staying asleep

Submission date
09/12/2024

Recruitment status
No longer recruiting

Registration date
17/12/2024

Overall study status
Completed

Last Edited
02/02/2026

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The objective of this study is to investigate the safety and efficacy of Maizinol™ on sleep quality in a healthy population with difficulty falling asleep or staying asleep.

Who can participate?
Healthy adults aged 18 to 65 years old with difficulty falling asleep or staying asleep.

What does the study involve?
Maizinol™ will be compared to a placebo to investigate the safety and effects on sleep quality as assessed by questionnaires, an actigraphy and electroencephalogram (EEG) device during sleep to measure the total sleep time, REM sleep time, deep sleep time, light sleep time and awake duration.

What are the possible benefits and risks of participating?
A possible benefit of participation in this study includes improved sleep quality and sleep outcome. A risk of participation includes experiencing potential adverse events, such as gastrointestinal symptoms.

Where is the study run from?
KGK Science Inc. in London, Ontario, Canada.

When is the study starting and how long is it expected to run for?
May 2022 to November 2023

Who is funding the study?
KEB Nutraceuticals USA Inc.

Who is the main contact?
Erin Lewis, PhD, Scientific Director - Nutritional Sciences, elewis@kgkscience.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
22UNRCZ01

Study information

Scientific Title
A randomized, triple-blind, placebo-controlled, parallel clinical trial to investigate the safety and efficacy of Maizinol™ on sleep quality in a healthy population with difficulty falling asleep or staying asleep

Study objectives
Maizinol™ improves sleep quality in healthy adults with difficulty falling asleep or staying asleep compared to placebo.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/11/2022, Advarra Institutional Review Board (372 Hollandview Trail, Suite 300, Aurora, L4G 0A5, Canada; +1 905-727-7989; info@advarra.com), ref: Pro00067855

Primary study design
Interventional

Study design
Single-center randomized triple-blind placebo-controlled parallel-group-assignment clinical trial

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Quality of sleep in healthy adults with difficulty falling asleep or staying asleep

Interventions
Eighty healthy adults were planned to be randomized, with 40 participants randomized equally to Maizinol™ or placebo in a triple-blinded manner at a ratio of 1:1. Participants are instructed to take one oral capsule of Maizinol™ or placebo 60 minutes before bedtime for 28 days. Each participant was assigned a randomization code according to the order of the randomization list generated using ww.randomization.com. Enrolled participants were randomized to the different study arms at baseline.

Intervention Type
Supplement

Primary outcome(s)
The change in total sleep time, REM sleep time, deep sleep time, light sleep time, and awake duration are measured using an actigraphy and electroencephalogram (EEG) device from baseline at Day 28

Key secondary outcome(s)
The following measures are assessed from baseline at Day 14:
1. Blood levels of serotonin measured using high-performance liquid chromatography, and melatonin and gamma-aminobutyric acid (GABA) measured using enzyme-linked immunosorbent assay (ELISA)
2. Clinically significant changes in vital signs (blood pressure [BP] and heart rate [HR]) measured manually or using an automatic blood pressure monitor/sphygmomanometer
3. Clinically significant changes in aspartate aminotransferase (AST), measured using IFCC without pyridoxal phosphate
4. Clinically significant changes in alanine aminotransferase (ALT), measured using a ALT catalysing reaction between L-alanine and 2-oxoglutarate. The pyruvate formed is reduced by NADH in a reaction catalyzed by lactate dehydrogenase (LDH) to form L-lactate and NAD+.
5. Clinically significant changes alkaline phosphatase (ALP), measured using a colorimetric assay
6. Clinically significant changes total bilirubin, measured using the colorimetric diazomethod
7. Clinically significant changes creatinine, measured using an enzymatic method
8. Clinically significant changes electrolytes (Na, K, Cl) measured using Indirect Ion-Selective Electrode
9. Clinically significant changes random glucose measured using a UV test, with enzymatic reference method with hexokinase
10. Clinically significant changes estimated glomerular filtration rate (eGFR) measured using The Chronic Kidney Disease Epidemiology Collaboration studies equation
11. Clinically significant changes in white blood cell (WBC) count with differential neutrophils, lymphocytes, monocytes, eosinophils, basophils, measured using Flow Cytometry Method using Semiconductor Laser
12. Clinically significant changes in red blood cell (RBC) count, platelet count, immature granulocytes, nucleated RBC, RBC indices (mean corpuscular volume [MCV], and red cell distribution width [RDW]), measured using Hydro Dynamic Focusing (DC Detection) - Impedance Counting.
13. Clinically significant changes in hemoglobin, mean corpuscular hemoglobin (MCH), mean

corpuscular hemoglobin concentration (MCHC), and hematocrit, measured using SLS-Hemoglobin Method

Completion date
30/11/2023

Eligibility

Key inclusion criteria
1. Males and females between 18 and 65 years of age, inclusive, at screening
2. Females not of child-bearing potential, defined as those who have undergone a sterilization procedure (e.g. hysterectomy, bilateral oophorectomy, bilateral tubal ligation, complete endometrial ablation) or have been post-menopausal for at least 1 year prior to screening
Or,
Individuals of childbearing potential must have a negative baseline urine pregnancy test and agree to use a medically approved method of birth control for the duration of the study.
All hormonal birth control must have been in use for a minimum of three months. Acceptable methods of birth control include:
2.1. Hormonal contraceptives including oral contraceptives, hormone birth control patch (Ortho Evra), vaginal contraceptive ring (NuvaRing), injectable contraceptives (Depo-Provera, Lunelle), or hormone implant (Norplant System)
2.2. Double-barrier method
2.3. Intrauterine devices
2.4. Non-heterosexual lifestyle or agrees to use contraception if planning on changing to heterosexual partner(s)
2.5. Vasectomy of partner at least 6 months prior to screening
3. Self-reported difficulty in falling asleep (taking longer than 30 minutes to fall asleep) or staying asleep, with two or more difficulty falling asleep/waking episodes in a 7-day period for at least one month
4. Agrees to maintain current lifestyle habits as much as possible throughout the run-in and study period depending on your ability to maintain the following: diet, medications, supplements, exercise, and avoid taking any new supplements
5. Agrees to stay in the current time zone for the duration of the run-in and study period
6. Agrees to refrain from herbal teas affecting sleep within 2 hours of bedtime, unless currently a part of their night routine for more than 30 days and willing to maintain that routine throughout the run-in and study period
7. Agrees to refrain from consuming caffeine and other stimulants, such as energy drinks, after 3: 00 pm for the duration of the run-in and study period
8. Willingness to provide information related to COVID-19 infection/vaccination history
9. Willingness to complete study procedures, assessments, and all clinic visits associated with this study
10. Provided voluntary, written, informed consent to participate in the study
11. Healthy as determined by medical history and laboratory results as assessed by the QI

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
79

Key exclusion criteria
1. Females who are pregnant, breast feeding, or planning to become pregnant during the study
2. Allergy, sensitivity, or intolerance to the IP or Placebo ingredients
3. Previous diagnosis of a sleep disorder or use of C-PAP
4. Menopausal women currently experiencing hot flashes
5. Current employment that calls for shiftwork or have worked shift work in the last three weeks
6. Travel across one or more time zones in the last two weeks prior to run-in
7. Currently experiencing vivid nightmares or sleepwalking
8. Unstable metabolic diseases or conditions known to cause disruptive sleep as assessed by the QI
9. Current or history of any significant psychiatric conditions, as assessed by the QI
10. Significant cardiovascular event in the past 6 months. Participants with no significant cardiovascular event on stable medication may be included after assessment by the QI on a case-by-case basis
11. Unstable hypertension. Treatment on a stable dose of medication for at least three months will be considered by the QI
12. Type I diabetes
13. Type II diabetes with HbA1c ≥ 7.5%
14. Self-reported confirmation of current or pre-existing thyroid condition. Treatment on a stable dose of medication for at least three months will be considered by the QI

Date of first enrolment
14/01/2023

Date of final enrolment
11/02/2023

Locations

Countries of recruitment
Canada

Study participating centre
KGK Science Inc.
275 Dundas Street Tower A Suite G02

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Sponsor information

Organisation
Unigen Inc

Funder(s)

Funder type
Industry

Funder Name
Unigen Inc

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be stored in a non-publicly available repository (Microsoft SharePoint). Participant EEG data is owned entirely by the sponsor and participant consent was obtained. Data is accessible to Unigen Inc. and KGK Science Inc. researchers and will not be shared.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/01/2026	02/02/2026	Yes	No
Participant information sheet	version 22	18/11/2022	17/12/2024	No	Yes