ISRCTN16548309 https://doi.org/10.1186/ISRCTN16548309

Effects of Lasoperin™ on cognitive function in healthy adults

Submission date 07/11/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/11/2023	**Overall study status** Completed	
Last Edited 20/12/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Nutrasource is a contract research organization (CRO) that specializes in conducting clinical trials with food, natural health products, pharmaceuticals, and other health products. Nutrasource is working with Chad Kerksick, PhD and the team at Lindenwood University, as well as the sponsor (Unigen, Inc.) to perform a research study to assess the effects of a dietary supplement on cognitive function in healthy adults.
Cognitive decline is a growing issue that can range from mild cognitive impairment to dementia. Currently there is no known cure for dementia and cognitive decline. Lifestyle changes (diet and exercise) are the only treatment that can lower dementia risk and prevent overall cognitive decline. Current pharmacological (drug) treatment is the use of cholinesterase inhibitors and memantine, which improve quality of life but do not stop disease progression. There is a protective effect of consuming nonsteroidal anti-inflammatory drugs (NSAIDs) against cognitive decline, however, they are not recommended for chronic use due to negative side effects. Dietary supplements may fill the role of NSAIDs by reducing cognitive decline later in life without the negative side effects. This study aims to evaluate the test product, Lasoperin™, for its impacts on cognitive function, well-being and mood, inflammation, brain health, oxidative stress, and quality of life in healthy adults.

Who can participate?
Healthy men and women between the ages of 30-60 years.

What does the study involve?
Your complete participation in this study will involve four separate visits with investigators that are anticipated to span 8 weeks.Throughout this study you will be asked to refrain from eating or drinking any food or drink that contains calories for 8 hours before arriving for testing in the laboratory. During your initial visit, you will need to complete your consent form, ask any questions about the study and be given instructions on how to complete the study protocols. Participants with childbearing potential will be asked that they or their partner practice a form of birth control (abstinence, tubal ligation, vasectomy, progestin arm implant, intrauterine device, oral contraceptives, progestin injection, male condoms, diaphragm, cervical cap, female condom, sponge, spermicides, etc) and must have a negative urine pregnancy test at the baseline study visit if you are of childbearing potential. You will have blood drawn during Visit 2,

Visit 3 and Visit 4. The amount of blood collected each time will be equal to approximately four teaspoons. The total amount of blood collected during the study is less than a quarter cup. In comparison, the amount of blood donated at a blood drive is eight times more than the amount of blood that will be removed for the entire 4-week study.
You will be assigned to ingest either a dietary supplement or a placebo in a double-blind fashion. This means that you will not know which supplement you are taking, and study investigators will not know which supplement you are taking. Both the test product and placebo will be in gelatin capsules. The placebo will be composed of either rice flour or a maltodextrin carbohydrate. If you are currently taking another dietary supplement that may impact cognitive function, you will be asked to discontinue use of the supplement for 14 days prior to starting the study. You will be asked to refrain from taking any dietary supplement suggested to impact cognitive function (e.g., Cannabidiol, Kava, St. John's wort, Ginkgo biloba, Acetyl-L-Carnitine, Bacopa monnieri, etc), S. baicalensis, A. catechu, and both medical and recreational cannabis for 2 weeks before starting the study and for the duration of the study. You will be asked to consume your assigned supplement for 4 weeks after your first visit to the lab until you complete all testing. All doses of your assigned supplement are to be ingested at the same time of day with water and not within 2 hours of consuming a meal.

What are the possible benefits and risks of participating?
You will receive no direct benefits for completing this survey. We hope what we learn may benefit other people in the future.
One risk from participation in this study stems largely from people being able to identify you through unique identifiers such as age, height, weight, ethnicity, race, etc. that researchers will collect and report on. Every effort will be made to keep your information secure. Only members of the research team will be able to see any data that may identify you. Additionally, all your data will be de-identified with a randomly assigned alphanumeric code. Only members of the research team will be able to see this code.
We will be collecting data from you using surveys we have created and posted on the internet. We take every reasonable effort to maintain security. Only your randomly assigned alphanumeric code will be used to identify your results. It is always possible that information during this research study may be captured and used by others not associated with this study.
A total of three blood samples will be collected from you during your involvement in this project. While the taking of blood samples may increase your discomfort and allow for the possibility of infection, we will ensure that you are in a comfortable, safe, and sanitary environment during all blood collection protocols. The risk of infection will be minimized by ensuring that all research team members are trained in effective phlebotomy techniques, thorough disinfecting of the laboratory environment, as well as proper handling and disposal of all phlebotomy devices.
In some cases, the supplement may cause gastrointestinal discomfort or distress. If you experience nausea, vomiting, or illness, contact the research team immediately so that we can determine whether to discontinue your involvement in the study.
The risk of contracting and spreading COVID-19 will be minimized by the development and following of the EPNL's "COVID-19 Exposure Control SOP" as well as following guidelines set forth by Lindenwood University. Our exposure control plan takes into account social distancing, rearranging the lab to allow for more space so team members and participants can spread out more efficiently, COVID-19 training documents, required PPE to be worn, and tracking symptoms for both team members and participants.

Where is the study run from?
The Exercise and Performance Nutrition Laboratory at Lindenwood University (USA)

When is the study starting and how long is it expected to run for?
January 2022 to October 2022

Who is funding the study?
Unigen, Inc. (USA)

Who is the main contact?
Chad M. Kerksick, ckerksick@lindenwood.edu

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Chad Kerksick

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Additional identifiers

Protocol serial number
U01-21-01-T0029

Study information

Scientific Title
A prospective, randomized, double-blind, placebo-controlled study to evaluate the effects of lasoperinTM on cognitive function in healthy adults

Acronym
COG

Study objectives
Lasoperin™ improves cognitive function, well-being and mood, inflammation, brain health, oxidative stress, and quality of life in healthy adults.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/03/2022, Lindenwood University Institutional Review Board (209 S Kingshighway St, St. Charles, 63301, United States of America; +1 (0)636 949 4155; IRB@lindenwood.edu), ref: IRB-22-78

Study design
Prospective randomized placebo-controlled double-blind trial

Primary study design
Interventional

Study type(s)
Quality of life, Safety, Efficacy

Health condition(s) or problem(s) studied
Cognitive function, well-being and mood, inflammation, brain health, oxidative stress, and quality of life in healthy adults

Interventions
In a randomized, double-blind, placebo-controlled fashion, study participants will be required to ingest either a placebo or supplement (Scutellaria baicalensis [241 mg] and Acacia catechu extracts [51 mg]. All participants will consume 1 dose (1 capsule) of their assigned supplement daily for 30 days.

Intervention Type
Supplement

Primary outcome(s)
Cognitive function is measured using the Flanker Inhibitory Control and Attention Test, Dimensional Change Card Sort Test, and Pattern Comparison Processing Speed Test at baseline, 2 weeks, and 4 weeks.

Key secondary outcome(s))
1. Well-bring and mood measured using the NIH Toolbox General Life Satisfaction Questionnaire at baseline, 2 weeks, and 4 weeks
2. Cognitive interference, visual attention, and motor functioning measured using the Stroop color test, Trail Making Test Part A and B, and Finger Tapping Test at baseline, 2 weeks, and 4 weeks
3. Inflammation, brain health, and oxidative stress measured using plasma C-Reactive protein (CRP), plasma cortisol, plasma brain-derived neurotrophic factor (BDNF), and serum uric acid at baseline, 2 weeks, and 4 weeks
4. Quality of life measured using the RAND 36-item short form (SF-36) survey at baseline, 2 weeks, and 4 weeks

Completion date
18/10/2022

Eligibility

Key inclusion criteria

1. Healthy adult participants who are 30 to 60 years of age (inclusive)
2. In good general health (no active or uncontrolled diseases or conditions)
3. Have a body mass index (BMI) between 18.0 to 34.9 kg/m² (inclusive)
4. Have normal or acceptable to the investigator vital signs (blood pressure and heart rate) at screening and/or baseline
5. Individuals with childbearing potential must agree to practice an acceptable form of birth control for a certain timeframe prior to the first dose of the study product and throughout the study, including:
5.1. Use for at least 3 months prior to the first dose of study product: hormonal contraceptives including oral contraceptives, hormone birth control patch (e.g., Ortho Evra), vaginal contraceptive ring (e.g., NuvaRing), injectable contraceptives (e.g., Depo-Provera, Lunelle), or hormone implant (e.g., Norplant System); or
5.2. Use for at least 1 month prior to the first dose of study product: double-barrier method, intrauterine devices, or complete abstinence from sexual intercourse that can result in pregnancy; or
5.3. Vasectomy of partner at least 6 months prior to the first dose of study product.
Individuals with the potential to impregnate others must agree to use condoms or other acceptable methods to prevent pregnancy throughout the study. Complete abstinence from sexual intercourse that can result in pregnancy is also acceptable.
6. Agree to refrain from treatments listed in Section 6.4 in the defined timeframe.
7. Willing to refrain from changing their diet or lifestyle significantly for the duration of the study.
8. Willing and able to agree to the requirements and restrictions of this study, be willing to give voluntary consent, be able to understand and read the questionnaires, and carry out all study-related procedures.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit
60 years

Sex
All

Total final enrolment
85

Key exclusion criteria
1. Participants who are lactating, pregnant or planning to become pregnant during the study
2. Have a known sensitivity, intolerability, or allergy to any of the study products or their excipients, or any of the rescue medications

3. Received a vaccine for COVID-19 in the 2 weeks prior to screening or during the study period, current COVID-19 infections, or currently have the post COVID-19 condition as defined by World Health Organization (WHO) (i.e., individuals with a history of probable or confirmed SARS-CoV-2 infection, usually 3 months from the onset of COVID-19 with symptoms that last for at least 2 months and cannot be explained by an alternative diagnosis).
4. Participants with diagnosed type I or type II diabetes
5. Having a history of heart disease, uncontrolled high blood pressure (≥140 mmHg systolic or ≥90 mmHg diastolic), renal or hepatic impairment/disease, major affective disorders, hepatic or renal dysfunction, unstable thyroid disease, immune disorders and/or immunocompromised (e.g. HIV/AIDS), cognitive impairment, neurological condition, or neurological disease, psychiatric disorder that required hospitalization in the past year, cancer (except localized skin cancer without metastases or in situ cervical cancer) within 5 years prior to the screening visit, or any clinically significant disease or disorder which, in the opinion of the investigator, may either put the potential participant at risk because of participation in the study, or influences the results or the potential participant's ability to participate in the study.
6. Major surgery in 3 months prior to screening or planned major surgery during the course of the study
7. Participant has a pacemaker or implantable cardiac defibrillator
8. Participant has an abnormality or obstruction of the gastrointestinal tract precluding swallowing (e.g. dysphagia) and digestion (e.g. known intestinal malabsorption, celiac disease, inflammatory bowel disease, chronic pancreatitis, steatorrhea)
9. Participant has a history of alcohol or substance abuse in the 12 months prior to screening
10. Receipt or use of test product(s) in another research study within 28 days prior to baseline or longer if the previous test product is deemed by the investigator to have lasting effects that might influence the eligibility criteria or outcomes of the current study
11. Any other active or unstable medical conditions or use of medications/supplements /therapies that, in the opinion of the investigator, may adversely affect the participant's ability to complete the study or its measures or pose a significant risk to the participant

Date of first enrolment
03/06/2022

Date of final enrolment
20/09/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Lindenwood University, Exercise and Performance Nutrition Laboratory
209 S. Kingshighway
St Charles
United States of America
63301

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 analysed during the current study will be available upon request from Chad M. Kerksick, PhD (ckerksick@lindenwood.edu)
Data will be available a minimum of 7 years from completion of the study
Informed consent was obtained from all participants, by having them sign an IRB-approved informed consent document.
All data will be de-identified using study identification codes.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/12/2024	20/12/2024	Yes	No