ISRCTN16835354 https://doi.org/10.1186/ISRCTN16835354

Does one-time ashwagandha intake improve cognitive function?

Submission date
31/10/2021

Recruitment status
No longer recruiting

Registration date
02/11/2021

Overall study status
Completed

Last Edited
03/01/2023

Condition category
Other

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

Plain English Summary
Background and study arms
Ashwagandha (ASH) has long been used in the traditional Ayurvedic system of medicine to enhance memory and improve cognition. Human intervention studies have linked Ashwagandha to increased cognition in patients with early dementia or bipolar disorder, but studies in healthy populations are limited. It is currently unknown if one-time supplementation with Ashwagandha can improve cognitive performance in young healthy adults. The aim of this study is to examine the effect of acute ingestion of 400 mg of ashwagandha on executive function including general attention, sustained attention, attentional shifting, and/or working memory in young adults.

Who can participate?
Healthy men and women between the ages of 18 to 59 years

What does the study involve?
Participants will be randomly allocated to receive ASH or placebo (dummy) capsules, and then perform four cognitive function tests that assess a range of cognitive and executive function aspects.

What are the possible benefits and risks of participating?
The potential benefit of participating is an increase in executive functioning.

Where is the study run from?
Texas A&M University (USA)

When is the study starting and how long is it expected to run for?
April 2019 to November 2019.

Who is funding the study?
Specnova Inc. (USA)

Who is the main contact?
Dr Richard B. Kreider
rbkreider@tamu.edu

Contact information

Type(s)
Scientific

Contact name
Prof Richard Kreider

ORCID ID
http://orcid.org/0000-0002-3906-1658

Contact details
Texas A&M University
675 Kimbrough Blvd.
Building #1542
College Station, TX
United States of America
77843-4253
+1 (0)979 458 1498
rbkreider@tamu.edu

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AcuteAshwagandha2019

Study information

Scientific Title
The effect of acute ashwagandha supplementation on cognitive function

Study hypothesis
Acute ashwagandha extract improves cognition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/07/2019, Texas A&M University Institutional Review Board (517 Blocker Building, 155 Ireland Street, Texas A&M University, College Station, TX 778431, USA; +1 (0)979 458 4067; irb@tamu.edu), ref: IRB2019-0453D

Study design
Interventional double-blinded randomized crossover controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available

Condition
Improving cognition in healthy individuals

Interventions
Subjects consumed capsules containing 400 mg of a proprietary root and leaves extract of ashwagandha (NooGandha®, Specnova, Boca Raton, FL, USA) or capsules containing 400 mg of a wheat flour placebo (Placebo) once they have completed baseline testing with 8 ounces of water. A computer generated randomization to treatment was used. Once subjects were randomized to start, they followed the counter balance progression.

Intervention Type
Supplement

Primary outcome measure
The Psychology Experiment Building Language (PEBL) software program (Version 2.1, http://pebl.sourceforge.net) was used to administer four cognitive function tests that assessed a range of cognitive and executive function aspects:
1. Berg-Wisconsin Card Sorting Task test (BCST) at baseline, 1, 2, 3, 4, 5 and 6 hours after ingestion
2. The Go/No-Go test (GNG) at baseline, 1, 2, 3, 4, 5 and 6 hours after ingestion
3. Sternberg Task Test (STT) at baseline, 1, 2, 3, 4, 5 and 6 hours after ingestion
4. Psychomotor Vigilance Task Test (PVTT) at baseline, 1, 2, 3, 4, 5 and 6 hours after ingestion

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/04/2019

Overall study end date
10/11/2019

Eligibility

Participant inclusion criteria
Apparently healthy males and females between the ages of 18 to 59 years were recruited to participate in the study.
All subjects were healthy and free from known:
1. Cognitive deficit conditions
2. Wheat flour allergies
3. Sleep disorders
4. Cardiovascular, metabolic, or pulmonary diseases
5. History of hypertension, migraine headaches, cardiac arrhythmias, or anxiety
6. Gastrointestinal reflux disease or ulcers

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
59 Years

Sex
Both

Target number of participants
15

Total final enrolment
15

Participant exclusion criteria
Subjects who were taking prescription medications in the month prior to the initiation of the study and/or were told by a physician to abstain or restrict caffeine and/or stimulant intake

Recruitment start date
20/07/2019

Recruitment end date
10/11/2019

Locations

Countries of recruitment
United States of America

Study participating centre
Texas A&M University
675 Kimbrough Blvd
Building #1542
College Station, Texas
United States of America
77843-4253

Sponsor information

Organisation
Specnova Inc.

Sponsor details
8609 Westwood Center Drive #110
Tysons Corner, VA
United States of America
22182
+1 (0)720 245 4096
sebastian@specnova.com

Sponsor type
Industry

Website
https://www.specnova.com

Funder(s)

Funder type
Industry

Funder Name
Specnova Inc.

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed scientific journal.

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

All data generated or analyzed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/09/2022	03/01/2023	Yes	No