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Effects of paraxanthine on brain function

Submission date	Recruitment status	[_] Prospectively registered
13/09/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/09/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/11/2021	Other	

Plain English summary of protocol

Background and study arms
Paraxanthine (1,7-dimethylxanthine, PX) is a natural dietary component that can be found in different parts of Theobroma cacao fruits, in Coffea arabica, in the rhizome and stem of Sinomenium actum, a traditional Chinese herbal medicine, and in the stamens of citrus flowers. PX is the major metabolite of caffeine in humans and is less toxic than caffeine. The potential beneficial effects of acute PX ingestion on executive function in healthy individuals are currently unknown. In this study, we are investigating the effects of 200mg of acute PX ingestion in comparison to placebo.

Who can participate?
Healthy males and females between the ages of 18 to 59 years

What does the study involve?
Participants will be randomly allocated to receive PX or placebo 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?
Potential benefits of participating is an increase in executive functioning. The ingestion of 200 mg of paraxanthine would be less than obtained from consuming a premium cup of coffee or energy drink.

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 July 2019 to November 2019.

Who is funding the study?
Ingenious Ingredients L.P., Lewisville, TX (USA)

Who is the main contact?
Richard B. Kreider, PhD, FACSM, FASEP, FISSN, FACN, FNAK, rbkreider@tamu.edu

Contact information

Type(s)
Scientific

Contact name
Prof Rick 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
+1 979-458-1498
rbkreider@tamu.edu

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
0453D

Study information

Scientific Title
Effects of acute ParaXanthine ingestion on Executive Function

Acronym
PXEF

Study objectives
Paraxanthine (1,7-dimethylxanthine, PX) increases executive functioning.

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; +1 979-458-4067; 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

Health condition(s) or problem(s) studied
Improving executive functioning in healthy individuals

Interventions
Subjects consumed capsules containing 200 mg of paraxanthine (ENFINITY™, Ingenious Ingredients L.P., Lewisville, TX, USA) or capsules containing 200 mg of a wheat flour placebo (Placebo) once they have completed baseline testing. One capsule of the PLA or PX 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

Completion date
10/11/2019

Eligibility

Key inclusion criteria
Apparently healthy males and females between the ages of 18 to 59 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

Sex
Both

Target number of participants
14

Total final enrolment
14

Key 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 were excluded from the present study.

Date of first enrolment
20/07/2019

Date of final enrolment
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
Ingenious Ingredients L.P.

Sponsor details
2560 King Arthur Blvd. Suite 124-74
Lewisville
United States of America
75056
+1 (704) 619-1692
info@ingeniousingredients.com

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Ingenious Ingredients, L.P.

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 analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/11/2021	19/11/2021	Yes	No