ISRCTN10054466 https://doi.org/10.1186/ISRCTN10054466

A study with healthy adults to compare how the body processes a dose of two different Kava root products

Submission date	Recruitment status	[_] Prospectively registered
24/10/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/11/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/11/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is looking at how two different types of kava root products behave in the body after a single dose. Kava is a plant traditionally used in the South Pacific to help with stress and anxiety. It's now used in other parts of the world too. Researchers want to compare a traditional kava drink made from dried roots with a kava paste extract used in a U.S. product. The goal is to understand how each type is absorbed and processed in the body, and to check if they are safe.

Who can participate?
Healthy adults aged 21 to 55 years can take part in the study.

What does the study involve?
Participants will try both kava products, one at a time, with a break of about 2 to 3 weeks in between. They'll be randomly assigned to start with one product and then switch to the other. The study includes several visits over a period of 3 to 8 weeks.

What are the possible benefits and risks of participating?
There are no direct personal benefits from taking part. However, the study may help improve understanding of how kava works and how safe it is. As with any study, there may be some side effects or health risks, which will be carefully monitored.

Where is the study run from?
ApexTrials, Canada.

When is the study starting and how long is it expected to run for?
October 2025 to December 2025

Who is funding the study?
Jerry Ross

Who is the main contact?
Dr Anthony Bier, MD., abier@apextrials.com

Contact information

Type(s)
Scientific

Contact name
Dr Stephanie-Anne Girard

Contact details
120 Research Lane
Guelph
Canada
N1G 0B4
+1 519-341-3367
sgirard@nutrasource.ca

Type(s)
Principal investigator

Contact name
Dr Anthony Bier

Contact details
Suite 101
120 Research Street
Guelph
Canada
N1G 0B4
+1 226-706-2545
abier@apextrials.com

Type(s)
Public

Contact name
Mrs Caroline Crudeli Sclearuc Haiashi

Contact details
120 Research Lane
Guelph
Canada
N1G 0B4
+1 5193413367
chaiashi@nutrasource.ca

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
B05-25-01-T0082

Study information

Scientific Title
A randomized, open-label, 2-period crossover study in healthy participants to compare the single dose pharmacokinetics of two kava root products

Study objectives
1. To compare the single dose PK profiles of two(2) Kava root products.
2. To assess the safety of a single dose of two (2) Kava root products

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/10/2025, Sterling IRB (5500 Interstate North Pkwy Ste 515, Atlanta, GA 30328, United States of America; +1-888-636-1062; selam.ghebru@sterlingirb.com), ref: 14526

Study design
Interventional randomized open-label single-center 2-period crossover study

Primary study design
Interventional

Study type(s)
Safety, Other

Health condition(s) or problem(s) studied
Pharmacokinetics study in healthy adults

Interventions
Study Duration: The entire study duration for each participant in each arm is approximately 3-8 weeks.
a. Screening period up to 28 days
b. 2 PK visits per test period (Periods A and B; PK Day 1 is approximately 14 hours; PK Day 2 is approximately 1 hour)
c. A washout period between test periods of 14 to 24 days
Follow-up Duration: The study is considered completed at the last study visit for the last participant or 30 days after the onset of last ongoing AE, whichever is later.
A Randomization Scheme is prepared by CRO based on a computer-generated algorithm (SAS). Each participant’s study product assignments will be associated with a unique code to prevent unblinding.

Intervention Type
Supplement

Primary outcome(s)
1. Area under the plasma concentration-time curve from time zero to last measurable concentration (AUC_{0}–t) for kavalactones is measured using validated LC-MS/MS assay at Visit 2, Visit 3, Visit 4, and Visit 5
2. Maximum plasma concentration (Cmax) of kavalactones is measured using validated LC-MS /MS assay at Visit 2, Visit 3, Visit 4, and Visit 5
3. Time to reach maximum plasma concentration (Tmax) of kavalactones is measured using validated LC-MS/MS assay at Visit 2, Visit 3, Visit 4, and Visit 5
4. Area under the plasma concentration-time curve from time zero to infinity (AUCinf) for kavalactones is measured using validated LC-MS/MS assay at Visit 2, Visit 3, Visit 4, and Visit 5
5. Terminal elimination half-life (T½) of kavalactones is measured using validated LC-MS/MS assay at Visit 2, Visit 3, Visit 4, and Visit 5
6. Elimination rate constant (Kel) of kavalactones is measured using validated LC-MS/MS assay at Visit 2, Visit 3, Visit 4, and Visit 5

Key secondary outcome(s))
Safety outcome measures:
1. Systolic and diastolic blood pressure is measured using automated sphygmomanometer at Visit 1, Visit 2, Visit 3, Visit 4, and Visit 5/ET
2. Heart rate is measured using automated sphygmomanometer at Visit 1, Visit 2, Visit 3, Visit 4, and Visit 5/ET
3. Haematology parameters are measured using standard full blood count panel at Visit 1, Visit 2, Visit 3, Visit 4, and Visit 5/ET
4. Clinical chemistry parameters are measured using standard biochemistry panel at Visit 1, Visit 2, Visit 3, Visit 4, and Visit 5/ET
5. Liver function parameters are measured using standard liver function test panel at Visit 1, Visit 2, Visit 3, Visit 4, and Visit 5/ET
6. Renal function parameters are measured using standard renal function test panel at Visit 1, Visit 2, Visit 3, Visit 4, and Visit 5/ET
7. Adverse events are measured using spontaneous participant report and investigator assessment at Visit 1, Visit 2, Visit 3, Visit 4, and Visit 5/ET

Completion date
25/12/2025

Eligibility

Key inclusion criteria
1. Adults who are 21 to 55 years of age (inclusive).
2. In good general health (i.e., no uncontrolled diseases or conditions) as deemed by the investigator (based on review of medical history, vital signs, laboratory safety tests, and physical examination performed at screening and/or before the first dose of study product).
3. Are able to consume the study product completely within the specified timeframe.
4. Not currently using, defined as ≤ 3 uses in the past 3 months prior to Visit 2, any nicotine-containing products (patches, gums, vapes, etc.), kava products, and/or kratom products, and willing to abstain starting 14 days prior to Visit 2 and throughout the study.
5. Have a BMI between 18.5 to 29.9 kg/m^2 (inclusive) and a body weight of ≥ 50 kg at screening and baseline (Visit 2).
6. Agree not to donate blood until 3 months after the study completion.
7. Must have suitable veins for repeated venipuncture.

8. Have maintained consistent dietary habits, including supplement intake, and lifestyle for the last 3 months before screening and agree to maintain them throughout the study.
9. Agree to follow the restrictions on concomitant treatments
10. Agree to follow the restrictions on lifestyle
11. Agree to use acceptable contraceptive methods
12. Willing and able to agree to the requirements of this study, be willing to give voluntary consent, and carry out all study-related procedures.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
21 years

Upper age limit
55 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Individuals who are lactating, pregnant, or planning to become pregnant during the study or demonstrate a positive pregnancy test at Visits 1 or 2.
2. Have a known sensitivity, intolerability, or allergy to any of the study products or their excipients.
3. Demonstrates a positive urine drug screen test at Visits 1 or 2, a positive urine cotinine test at Visit 2, or a positive breath alcohol test at Visit 2.
4. Individuals with 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).
5. Screening laboratory results showing liver enzyme levels [Alanine Transaminase (ALT), Aspartate Transaminase (AST), Alkaline Phosphatase (ALP), Gamma-Glutamyl Transferase (GGT), total bilirubin] that are ≥ 2 times the upper limit of normal, or any
other clinically significant abnormal safety laboratory values as per the Investigator’s discretion.
6. Have Type I/II diabetes, high (≥140 systolic or ≥90 diastolic mmHg) or low (<90 systolic or <60 diastolic mmHg) BP at Visit 2, or thyroid disease.
7. Have a history of heart disease, blood clotting disorders, renal or hepatic impairment/disease, seizure disorders, epilepsy, or neurological disease.
8. Have known genetic polymorphisms of CYP450 enzymes, including CYP1A2, CYP2C9, CYP2C19, CYP2D6, CYP2B6, and/or CYP3A4.
9. Have medical condition(s) known to interfere with absorption, distribution, metabolism, or excretion of the study product (e.g., Crohn’s disease, short bowel, acute or chronic pancreatitis,

or pancreatic insufficiency).
10. Have a history of cancer (except localized skin cancer without metastases or in situ cervical cancer), unless recovery occurred more than 5 years before the screening visit.
11. Are receiving treatments for or have been hospitalized in the last 12 months for psychiatric disorders (e.g., depression, bipolar disorder, schizophrenia, etc.).
12. Reports significant blood loss or blood donation totaling between 101 mL and 449 mL of blood within 30 days prior to Visit 2 or a blood donation of more than 450 mL within 56 days prior to Visit 2.
13. Reports donating plasma (e.g., plasmapheresis) within 15 days prior to Visit 2.
14. Major surgery in the 3 months prior to screening or planned major surgery during the study.
15. Have a history of alcohol or substance abuse in the 12 months prior to screening (including having been hospitalized for such in an inpatient or outpatient intervention program) or use that, in the opinion of the investigator, may be of a concern for the study.
16. Currently consumes more than 2 standard alcoholic beverages a day. Note: A standard alcoholic beverage is defined as 12 ounces of beer, 5 ounces of wine, or 1.5 ounces of liquor.
17. Current enrollment or past participation in another study with any product(s) with at least one active ingredient within 28 days before the first dose of study product 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.
18. Any other medical condition/situation or use of medications/supplements/therapies that, in the opinion of the investigator, may adversely affect the participant's ability to participate in the study or its measures or pose a significant risk to the participant.

Date of first enrolment
17/10/2025

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
Canada

Study participating centre
ApexTrials
120 Research Lane, Suite 203
Guelph
Canada
N1G 0B4

Sponsor information

Organisation
Botanic Tonics, LLC

Funder(s)

Funder type
Other

Funder Name
Jerry Ross

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date