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Phyllantus amarus for the protection of liver health

Submission date	Recruitment status	[ ] Prospectively registered
15/11/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/02/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/09/2014	Digestive System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Phyllanthus amarus is a widespread tropical plant, traditionally used for general liver health. However, few studies have assessed the effects of Phyllanthus amarus, and none have examined its effects in relation to hangovers. In this study, Phyllpro, a standardized freeze-dried water extract of Phyllanthus amarus leaves, was evaluated for hangover symptoms and liver protection against temporary stress induced by alcohol consumption.

Who can participate?
Men and women of general good health, aged 21-50 and regularly consuming at least five servings of alcohol per week.

What does the study involve?
Participants received both of the following two treatments in a random order: Phyllpro or an identical placebo (dummy) drug twice daily for 10 days. We then measured hangover symptoms and the ability of the drug to protect the liver from oxidative damage and inflammation.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
The study was conducted at the Staywell Research clinical research site located in Northridge, CA, USA.

When is the study starting and how long is it expected to run for?
The study ran from July 2010 to October 2010.

Who is funding the study?
Biotropics Malaysia Berhad, Kuala Lumpur, Malaysia.

Who is the main contact?
Jay Udani, MD
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
BIOT1200

Study information

Scientific Title
Phyllantus amarus for the protection of liver heath: a randomized controlled trial

Study objectives
The purpose of this study is to assess the ability of Phyllantus amarus to protect the liver against temporary stress induced by alcohol consumption.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Initial IRB approval of the protocol was granted on 12/05/2010 by the Copernicus Group IRB (Cary, NC). Protocol Amendment was approved on 16/09/2010 by the Copernicus Group IRB (Cary, NC).

Primary study design
Interventional

Study design
Randomized double-blind placebo-controlled crossover study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Temporary liver stress induced by alcohol consumption

Interventions

PhyllPro, a propriety extract of Phyllanthus amarus 375 mg to be taken orally, one tablet twice daily for 10 days.

The placebo was a combination of inactive components, including microcrystalline cellulose, and it was also to be taken as one tablet twice daily for 10 days. There was an 11-day washout period between the two treatment periods.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Phyllanthus amarus

Primary outcome(s)
1. High Sensitivity C-reactive Protein (HS CRP)
2. Inflammatory Cytokine Panel [including TNF alpha, IL-1Beta, IL-2 , IL-4 , IL-5, IL-6 , IL-7, IL-8, IL-10 , IL-12p70, IL-13 , IL-17A, TNF-alpha , G-CSF , Eotaxin, MIP1Beta, IFNgamma, VEGF, MCP- 1, FGF-BASIC, GM-CSF]
3. Liver function tests [AST and ALT, total bilirubin, albumin, International Normalized ratio (INR), aspartate amino transferase, alanine amino transferase and alkaline phosphatase]

Key secondary outcome(s)
1. Hangover severity score: 7-point scale from none (0) to six (6). Healthy subjects should have a score of 0
2. Profile of Mood States (POMS)
3. Cognitive performance tests (CNS Vital Signs System)
4. Sleep Quality Scale

Completion date
16/10/2010

Eligibility

Key inclusion criteria
1. Healthy male or female 21-50 years of age, inclusive
2. Subject consumes at least five servings of alcohol per week on a regular basis. Liquor vs wine or beer
3. Minimum Profile of Mood States (POMS) score of 15
4. Access to a computer and internet
5. Subject is willing to maintain his or her habitual food and beverage intake (other than substitution of study food for similar products) and physical activity patterns throughout the study period
6. Body mass index (BMI) between 20 and 30 kg/m2
7. Subject is willing and able to comply with the alcohol consumption requirements
8. Subjects willing to stay in the clinic for two overnight stays
9. Generally healthy
10. Agree to all visits and study procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Any liver condition including hepatitis B, hepatitis C, fatty liver and liver disease
2. Liver function greater than three times the upper level limit of normal
3. History or record of aggressive or violent behavior
4. Evidence of liver disease
5. Presence of ascites
6. Family history of alcoholism
7. Any significant gastrointestinal (GI) condition that would potentially interfere with the evaluation of the study product [e.g.,ulcerative colitis or Crohns disease, inflammatory bowel disease, irritable bowel syndrome, clinically significant gastritis, celiac disease, gastroesophageal reflux disease (GERD), history of upper GI bleed (bleeding ulcer), chronic constipation (defined as <3 bowel movements per week), history of frequent diarrhea, history of surgery for weight loss, gastroparesis, clinically important lactose intolerance]
8. Clinically significant renal, hepatic, endocrine (including diabetes mellitus), cardiac, pulmonary, pancreatic, neurologic, or biliary disorder
9. Known allergy or sensitivity to any ingredients in the study products
10. Extreme dietary habits (e.g., vegan, Atkins Diet, etc.)
11. Recent (within two weeks of visit 1, week -1) episode of acute gastrointestinal illness such as nausea, vomiting, or diarrhea
12. Uncontrolled hypertension (systolic blood pressure _160 mm Hg or diastolic blood pressure _100 mm Hg at visit 1, week -1)
13. History or presence of cancer in the prior two years, except for non-melanoma skin cancer
14. Any major trauma or surgical event within three months of visit 1, week -1
15. Recent use of antibiotics (within 6 weeks)
16. Females who are pregnant, lactating, planning to be pregnant during the study period
17. Recent history of (within 12 months) or strong potential for alcohol or substance abuse
18. Alcohol abuse will be defined as >14 drinks per week (1 drink =12 ounces beer, 5 ounces wine, or 1 ½ ounces distilled spirits)
19. Participation in a clinical study with exposure to any non-registered drug product within 30 days prior
20. Individual has a condition the Investigator believes would interfere with his or her ability to provide informed consent, comply with the study protocol, which might confound the interpretation of the study results or put the person at undue risk
21. Current active respiratory illness at the time of screening
22. Any immune system disorders
23. Subjects with a history of perforation of the stomach or intestines
24. Subjects who have had gastric bypass surgery
25. Untreated hypothyroidism
26. Subjects with active eating disorder including anorexia nervosa, bulimia, and/or obsessive

compulsive eating disorders
27. Spinal cord injuries

Date of first enrolment
13/07/2010

Date of final enrolment
16/10/2010

Locations

Countries of recruitment
United States of America

Study participating centre
18250 Roscoe Blvd. Suite 220
Northridge, CA
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91325

Sponsor information

Organisation
Biotropics Malaysia (Malaysia)

ROR
https://ror.org/00jsvb253

Funder(s)

Funder type
Industry

Funder Name
Medicus Research (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration