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Comparing the effect of moderate daily consumption of cachaça and red wine on markers of heart disease in healthy volunteers

Submission date
11/10/2019

Recruitment status
No longer recruiting

Registration date
01/11/2019

Overall study status
Completed

Last Edited
05/12/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Cardiovascular (heart and blood vessel) disease remains the most common cause of death worldwide. Coronary atherosclerosis is when the blood vessels around the heart become blocked and stiffened. This is a major cause of cardiovascular disease. Drinking alcohol in moderate amounts has been shown to reduce inflammation, reduce blood clot formation and improve cholesterol levels, all of which are involved in atherosclerosis. It is known that moderate wine consumption is associated with improved cardiovascular health. Other studies have shown a similar effect for other alcoholic drinks such as beer and spirits. However it is not known whether the Brazilian spirit cachaça has the same effect. This study will investigate the levels of substances in the body that are associated with cardiovascular health or disease after periods of moderate consumption of cachaça and red wine, separately, in the same participants.

Who can participate?
Healthy adults who are willing to drink no alcohol for three separate weeks and to drink wine and cachaça daily at the required amounts for 28 days.

What does the study involve?
The participants will be randomly allocated to one of two groups. Both groups will have 7 days of not drinking any alcohol. One group will drink cachaça daily for 28 days and the other group will drink red wine daily for 28 days. Then both groups will drink no alcohol for 7 days, then the group who drank cachaça in the first period will drink red wine daily for 28 days and the the group who drank red wine in the first period will drink cachaça daily for 28 days.

What are the possible benefits and risks of participating?
There will be no payment for those wishing to participate in the study. Alcoholic beverages will be provided by the study. Side effects are the same as related to the consumption of any alcoholic beverage. The abuse of the beverages provided by the study is totally discouraged by the researchers.

Where is the study run from?
Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (HCFMUSP) [Hospital of the Faculty of Medicine of the University of Sao Paulo] (Brazil)

When is the study starting and how long is it expected to run for?
February 2018 to December 2020

Who is funding the study?
Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP) [Sao Paulo State Support for Research] (Brazil)

Who is the main contact?
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Additional identifiers

Protocol serial number
16758719.6.0000.0068

Study information

Scientific Title
Randomized clinical trial evaluating the effect on many molecular markers well established as atherosclerosis/cardiovascular risk factors of moderate different alcoholic beverages consumption on healthy subjects.

Acronym
WICAS

Study objectives
Could cachaça positively modify traditional cardiovascular biomarkers in the same proportion as wine?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/08/2019, Comissão de Ética para Análise de Projetos de Pesquisa do HCFMUSP [HCFMUSP Research Ethics Committee] (225 Rua Ovídio Pires de Campos, 5th floor, Prédio da Administração, São Paulo, Brazil; +55 2661-7585;cappesq.adm@hc.fm.usp.br), ref: 3.491.738

Primary study design
Interventional

Study design
Single-center, prospective, interventional, controlled, crossover study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Atherosclerosis

Interventions
This is a crossover study. Participants will be randomized using computer software to determine whether they consume red wine or cachaça in the first intervention period. Each participant will start with 7 days of abstinence from all alcohol , then a period of 28 days of moderate consumption of red wine or cachaça, then another 7 days of abstinence, then 28 days of the other alcoholic beverage. Beverages will be provided by the study organizers. They will consume 28 g of alcohol (2 servings, equivalent to 90 ml of cachaça 40% or 230 ml of 12% wine) per day for men and 14 g for women (1 serving per day) in the form of wine or cachaça. The total duration of treatment is 5 weeks and there is no additional follow-up.

Intervention Type
Other

Primary outcome(s)
C-reactive Protein (CRP) level in blood at days 7, 35, 42 and 70

Key secondary outcome(s)
1. Ultrasensitive Troponin level in blood at days 7, 35, 42 and 70
2. Interleukin 10 (IL-10) level in blood at days 7, 35, 42 and 70
3. Interleukin 6 (IL-6) level in blood at days 7, 35, 42 and 70
4. Apolipoprotein A1 (ApoA1) level in blood at days 7, 35, 42 and 70
5. Apolipoprotein B (ApoB) level in blood at days 7, 35, 42 and 70
6. Fasting glucose level in blood at days 7, 35, 42 and 70
7. Insulin level in blood at days 7, 35, 42 and 70
8. Fibrinogen level in blood at days 7, 35, 42 and 70
9. Total cholesterol and fractions levels in blood at days 7, 35, 42 and 70
10. Platelet aggregability test level using blood taken at days 7, 35, 42 and 70

Completion date
18/11/2020

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Able to drink alcohol
3. Able to abstain from alcohol for 1 week

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
42

Key exclusion criteria
1. Established cardiovascular disease, defined as documented atherosclerosis, previous cardiovascular event, myocardial revascularization, heart failure
2. Chronic use of corticosteroids, non-anti-inflammatory steroidal drugs (NSAIDs), statins, oral hypoglycemic agents, insulins, anticoagulants or antiplatelet agents
3. Inability to sign the free and informed consent form
4. History of alcoholism or inability to remain abstinent for the period established in the study
5. Refusal to drink alcohol for the period established
6. Pregnancy

Date of first enrolment
01/11/2019

Date of final enrolment
31/07/2020

Locations

Countries of recruitment
Brazil

Study participating centre
Instituto do Coração do Hospital das Clínicas de São Paulo (InCor)
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Sponsor information

Organisation
Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP)

ROR
https://ror.org/02ddkpn78

Funder(s)

Funder type
Government

Funder Name
Fundação de Amparo à Pesquisa do Estado de São Paulo

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
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/10/2022	05/12/2022	Yes	No