

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

<b>Submission date</b> 11/10/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/11/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/12/2022	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English Summary

### 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?

Pedro Henrique de Moraes Cellia, pedrohenriquemcellia@gmail.com

## Contact information

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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 hypothesis**

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

**Study design**

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

**Primary study design**

Interventional

**Secondary study design**

Randomised cross over trial

**Study setting(s)**

Community

**Study type(s)**

Prevention

**Participant information sheet**

Not available in web format, please use the contact details below to request a participant information sheet.

**Condition**

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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/02/2018

**Overall study end date**

18/11/2020

## Eligibility

**Participant 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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

40

**Total final enrolment**

42

**Participant 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

**Recruitment start date**

01/11/2019

**Recruitment end date**

31/07/2020

# Locations

## Countries of recruitment

Brazil

## Study participating centre

**Instituto do Coração do Hospital das Clínicas de São Paulo (InCor)**

Av. Dr. Enéas Carvalho de Aguiar, 44

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# Sponsor information

## Organisation

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

## Sponsor details

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## Sponsor type

Hospital/treatment centre

## Website

<http://www.incor.usp.br/sites/incor2013/>

## 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

## Publication and dissemination plan

To make data public on 2020 ESC congress

## Intention to publish date

31/07/2021

## 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?
<a href="#">Results article</a>		27/10/2022	05/12/2022	Yes	No