ISRCTN40313372 https://doi.org/10.1186/ISRCTN40313372

Short term effects of low caffeine energy drinks on blood vessel and heart functions in healthy volunteers

Submission date	Recruitment status	[ ] Prospectively registered
17/10/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/10/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/10/2021	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Caffeine is a natural stimulant most commonly found in tea, coffee, and cacao plants. It works by stimulating the brain and central nervous system, helping you stay alert and prevent the onset of tiredness.
High caffeine content energy drinks are known to have adverse health effects. Turkish law restricts the caffeine and taurine content of energy drinks.
This study aims to investigate the short-term effects of energy drinks on heart and blood vessel function.

Who can participate?
The study is open to healthy volunteers 18-50 years of age who are not heavy smokers or heavy caffeine consumers.

What does the study involve?
The volunteers will be given a 355 ml can of Red Bull energy drink containing 53.25 mg of caffeine and their measurements will be recorded before and after the energy drink consumption. They will also be given a control drink (mixed fruit juice) in another session where their measurements will also be recorded.

What are the possible benefits and risks of participating?
This study investigates the acute effects of commercially available limited caffeine energy drinks on heart and vessel functions. The results of the study might shed light on the potential benefits of restricting the caffeine and taurine content of commercially available energy drinks. The participants will drink only 355 ml of the study drinks once. There are no potential risks for participating in this study.

Where is the study run from?
Ankara University School of Medicine Cardiology Department (Turkey)

When is the study starting and how long is it expected to run for?
March 2014 to January 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Cansin Tulunay Kaya, kayac@ankara.edu.tr

Contact information

Type(s)
Scientific

Contact name
Dr Cansin Tulunay Kaya

ORCID ID
http://orcid.org/0000-0002-1168-9005

Contact details
Ankara University School of Medicine Department of Cardiology Samanpazarı
Ankara
Türkiye
06100
+90 3125082778
kayac@ankara.edu.tr

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ED-0001

Study information

Scientific Title
Acute effects of low caffeine energy drinks on endothelial and myocardial functions in healthy volunteers

Study objectives

Restricted caffeine and taurine content energy drinks might effect the endothelial functions adversely. Myocardial functions can improve after energy drink consumption

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/06/2014, Ankara University Clinical Trials Ethics Board (Ankara Universitesi Tip Fakultesi Morfoloji Binasi 06100 Sıhhiye/Ankara, Turkey; +90 312 595 8227; etik@medicine.ankara.edu.tr), ref: 11-484-14

Study design
Single center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Determining the effect of energy drink consumption on heart and blood vessel function in healthy volunteers

Interventions
The volunteers are assigned to study drinks through online randomization (randomizer.org) , they will be asked to drink 355 ml of one of the study drinks (commercially available energy drink containing 53.25 mg caffeine or control drink which is mixed fruit juice) and crossover to the other in two seperate sessions 7-10 days apart. The study ends after the second session.

Intervention Type
Other

Primary outcome measure
The change in endothelial flow mediated dilation (FMD) is measured before and 60 minutes after energy drink consumption.

Secondary outcome measures
The change in myocardial strain levels is measured using Echocardiographic images for 2 dimensional speckle tracking echocardiography of left and right ventricles recorded before and

60 minutes after study drink consumption, which are then analyzed offline by an investigator blind to patient data.

Overall study start date
10/03/2014

Completion date
01/01/2021

Eligibility

Key inclusion criteria
Healthy volunteers giving informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
34

Total final enrolment
34

Key exclusion criteria
1. Any abnormalities in their baseline screening echocardiographic examination
2. Heavy caffeine consumers (>200 mg/day)
3. Smoke >5 cigarettes/day
4. Low BMI (<18.5 kg/m²) or obese individuals (BMI>30 kg/m²)
5. Acute infection

Date of first enrolment
01/08/2014

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
Türkiye

Study participating centre

Ankara University School of Medicine Cardiology Department
Ibni Sina Hospital
Samanpazari
Ankara
Türkiye
06100

Sponsor information

Organisation
Ankara University

Sponsor details
School of Medicine
Cardiology department
Samanpazari
Ankara
Türkiye
06100
+90 3125082523
kardiyo@medicine.ankara.edu.tr

Sponsor type
University/education

Website
http://en.ankara.edu.tr/

ROR
https://ror.org/01wntqw50

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/01/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request from Dr Cansın Tulunay Kaya, kayac@ankara.edu.tr. The data will be anonymized before sharing.

IPD sharing plan summary
Available on request