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A study into the effects of 12 weeks of coffee drinking on non-coffee drinkers

Submission date
28/11/2013

Recruitment status
No longer recruiting

Registration date
14/01/2014

Overall study status
Completed

Last Edited
04/04/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
There is evidence from studies in populations which suggests that people who drink coffee are less likely to develop Type 2 Diabetes Mellitus (T2DM) than those who dont. However, short-term studies, which look at the effect of coffee on blood glucose over a period of several hours, have had varying results. It is possible that any beneficial effects of coffee in terms of diabetes risk are not as a result of its effects on blood glucose and insulin but by its effects on other factors associated with risk of T2DM such as cholesterol, raised triglycerides (fat/lipids), obesity and high blood pressure.
There have been few studies looking at the longer term effects of coffee drinking. Of these, most have used regular coffee drinkers. However, this may not be the best group of people to study as they will probably already have gained any benefits associated with long-term coffee drinking.
Research has also shown that the effects of coffee drinking on certain disease risks may vary depending on how the individual deals with caffeine; however, this has not so far been investigated in relation to diabetes risk.
This study therefore aims to investigate the effects in non-coffee drinkers of drinking four cups of coffee per day over a 12-week period on various risk factors for T2DM. We will also investigate whether these effects vary depending on whether the participants are fast or slow caffeine metabolisers .

Who can take part?
Healthy non-smoker males and females aged 18 and over who have had a stable weight for 3 months and who do not drink tea or coffee regularly.

What does the study involve?
At the first study visit a fasting blood sample is taken from the participant. The participant is then fed a liquid meal and further blood samples are taken at 15, 30, 60, 90 and 120 minute intervals. Participants are randomly allocated to either a coffee-drinking or caffeine-free group. The coffee-drinking group drink four cups of caffeinated coffee per day for 12 weeks. The caffeine-free group are caffeine free for 12 weeks. Participants will be visited 2-3 times during

the 12 weeks and asked to provide saliva samples which will be tested to check if participants in each group are following the set procedures . The participant then returns for a second study visit, which is identical to the first.

What are the possible benefits and risks of participating?
There are no anticipated benefits. There is a risk of an adverse reaction to coffee, such as shaking, difficulty getting to sleep and abnormal heartbeats. This will be minimised by spreading the coffee drinking throughout the day and drinking the last cup before 5pm. Participants will also take part in a two-day study before enrolment into the full study.

Where is the study run from?
University of Surrey (UK).

When is the study starting and how long is it expected to run for?
The study started in November 2013 and will run until December 2014.

Who is funding the study?
Biotechnology and Biological Sciences Research Council (BBSRC) (UK).

Who is the main contact?
Dr Denise Robertson

Contact information

Type(s)
Scientific

Contact name
Dr Denise Robertson

Contact details
University of Surrey
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GU2 7XH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A parallel arm study investigating the effects of 12 weeks coffee drinking in non coffee drinkers on glucose metabolism and other risk factors for Type 2 Diabetes Mellitus

Study objectives
Epidemiological evidence suggests that people who drink a lot of coffee are less likely to develop Type 2 Diabetes Mellitus (T2DM). Acute intervention studies investigating the effects of a single dose of coffee on the glycaemic response are contradictory. Any potential beneficial effects of coffee may however not manifest in an acute study, but may appear over a prolonged period of coffee drinking.

Variations in a gene responsible for caffeine metabolism mean that some people are slow caffeine metabolisers, whereas some are fast metabolisers. It is possible that these genetic variations will affect postprandial glucose metabolism; however, to date there have been no studies examining the effect of these genotypes on glycaemic response.

The aim of this study is to investigate the effects in non-coffee drinkers of consuming caffeinated coffee for 12 weeks on glucose metabolism and other risk factors for T2DM.

A secondary aim is to examine whether any effects found differ between slow and fast caffeine metabolisers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Surrey Ethics Committee, 25/07/2013, ref: EC/2013/68/FHMS

Study design
Randomised parallel arm intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Glucose metabolism

Interventions

Arm 1 (coffee intervention): four cups of coffee per day (made from 2 g instant coffee granules) for 12 weeks.
Arm 2 (control group): no caffeine and four cups of water per day for 12 weeks.

There will be no follow-up for either arm after the 12-week intervention and the final (second) study visit has taken place.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. 2-hour liquid meal tolerance test (glucose, insulin and triglycerides)
2. Fasting glucose
3. Insulin
4. Adiponectin
5. Inflammatory markers
6. Lipids

Measured at baseline and after 12-week intervention.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2013

Completion date
13/08/2015

Eligibility

Key inclusion criteria
1. Healthy adult males and females (aged 18+)
2. Weight stable for 3 months
3. People who do not drink tea and coffee regularly

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Those taking any prescription medicines (excluding contraceptives) within the last 3 months
2. Regular smokers
3. Regular tea and coffee drinkers
4. Medical conditions including heart disease, diabetes, gastrointestinal diseases, liver disease and endocrine diseases
5. Those following a weight-reducing diet

Date of first enrolment
30/09/2013

Date of final enrolment
09/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Surrey Clinical Research Centre
University of Surrey
Egerton Road
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
University of Surrey (UK)

Sponsor details
Research and Enterprise Support
Guildford
England
United Kingdom
GU2 7XH

Sponsor type

University/education

Website
http://www.surrey.ac.uk/

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Research organisation

Funder Name
Biotechnology and Biological Sciences Research Council (BBSRC) (UK) - CASE studentship

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal by the end of 2017.

Intention to publish date
31/12/2017

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

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018		Yes	No