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Metabolite Identification after Polyphenol Ingestion in Adults

Submission date	Recruitment status	[_] Prospectively registered
05/11/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/12/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/02/2019	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Catechins in tea and chlorogenic acids in coffee are chemicals called polyphenols that can help people maintain a healthy weight by increasing metabolism (the rate in which the body uses energy) but the effect varies between people. The aim of this study is to identify novel biomarkers which give information about a persons metabolic rate (metabolic status) after consumption of these polyphenols.

Who can participate?
Healthy male volunteers aged 20 to 59 years who are normal weight or overweight (body mass index 18.5-29.9 kg/m2).

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given coffee (which contains chlorogenic acids) to drink every day for 4 weeks. Those in group 2 are given green tea (which contains catechins) to drink every day for 4 weeks. Urine and blood samples are collected before and after drinking the tea or coffee with a cookie. After a break of two weeks or more, all participants repeat this process with a placebo (dummy) drink.

What are the possible benefits and risks of participating?
Participants will find out about how they react to the polyphenols and whether they could improve their metabolism by taking them. Risks of participating may include pain and, in some cases, internal bleeding during blood sampling.

Where is the study run from?
Tochigi Research Laboratories (Japan).

When is the study starting and how long is it expected to run for?
February 2014 to July 2014.

Who is funding the study?
Kao Corporation (Japan).

Who is the main contact?
Dr Akira Shimotoyodome

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
507-131203

Study information

Scientific Title
Metabolite Identification after Polyphenol Ingestion in Adults: a randomized double-blind placebo-controlled crossover study

Acronym
MIPIA

Study objectives
Dietary supplementation with tea catechins and coffee chlorogenic acids enhanced energy metabolism in humans. The aim of this study is to identify novel biomarkers in urine and blood which reflect metabolic status after consumption of dietary polyphenols in Japanese male adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Human Research Ethics Committee of Biological Science Laboratories of Kao Corporation, 19/12/2013, ref: 507-20131218

Study design
Randomized double-blind placebo-controlled crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Urine and blood biomarkers after consumption of dietary polyphenols

Interventions
Twenty subjects were randomized into either the coffee group or the green tea group (10 for each group). They ingested a test beverage including either 390 mg chlorogenic acids for the coffee group or 646 mg catechins for the green tea group per day for 4 weeks. At the time before and after the intervention period, indirect calorimetry was performed, and urine and blood samples were collected before and after ingestion of the test beverage with a cookie meal. Subjects ingested the test (coffee or green tea) and placebo beverages. There was the washout period of two weeks or more between the intervention period of the test and placebo beverages.

Intervention Type
Supplement

Primary outcome measure
Metabolomic profiles of urine and blood which associate with indirect calorimetry; Timepoints: baseline (before intervention period), after 4-week intervention period, fasting and postprandial states

Secondary outcome measures
Metabolomic profiles of urine and blood which associate with the polyphenol intake; Timepoints: baseline (before intervention period), after 4-week intervention period, fasting and postprandial states

Overall study start date
07/02/2014

Completion date
10/07/2014

Eligibility

Key inclusion criteria
1. Healthy volunteers aged 20 to 59 years
2. Male
3. Normal weight or overweight (body mass index 18.5-29.9 kg/m2)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
20

Key exclusion criteria
1. Caffeine intoxication
2. Food allergy
3. Intake of catechins or chlorogenic acid supplements
4. Serious illness (such as heart disease, kidney disease, diabetes and so on)

Date of first enrolment
07/02/2014

Date of final enrolment
10/07/2014

Locations

Countries of recruitment
Japan

Study participating centre
Tochigi Research Laboratories
2606 Akabane
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Sponsor information

Organisation
Kao Corporation (Japan)

Sponsor details
14-10
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103-8210

Sponsor type
Industry

Website
http://www.kao.com/jp/

ROR
https://ror.org/016t1kc57

Funder(s)

Funder type
Industry

Funder Name
Kao Corporation (Japan)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	01/11/2016		Yes	No
Results article	results	07/03/2019		Yes	No