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Influence of high dose cocoa-flavanol intake on factors affecting exercise performance and recovery

Submission date	Recruitment status	[ ] Prospectively registered
21/11/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/04/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/04/2017	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cocoa flavanols (CF) are a supplement made from cocoa beans. They have several beneficial health effects and can stimulate blood flow to provide the body with sufficient oxygen and nutrients when exercising. After exercise, the body needs to recover. The aim of this study is to find out whether taking this CF supplement can help to improve exercise performance and help recovery from exercise.

Who can participate?
Well-trained male cyclists aged 20 to 35

What does the study involve?
Participants undergo a cycling test on the first occasion. On two separate occasions, participants undergo two 30-min all-out cycling exercises (time trials), 1.5 and 3 hours after taking either CF or a placebo (dummy supplement), with a rest in between. Blood samples are taken at the start of the study and before and after each time trial and tested for several markers.

What are the possible benefits and risks of participating?
The possible benefits include improved performance and recovery from exercise. The study does not involve any risks, as the participants are used to heavy exercise and perform cycling training at least 10 hours per week.

Where is the study run from?
Vrije Universiteit Brussel (Belgium)

When is the study starting and how long is it expected to run for?
March 2015 to July 2015

Who is funding the study?
Vrije Universiteit Brussel (Belgium)

Who is the main contact?
Lieselot Decroix

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CFEX

Study information

Scientific Title
Effect of acute cocoa flavanols intake on exercise-induced oxidative stress, inflammation and nitric oxide production in healthy athletes: a randomized controlled trial

Study objectives
It is hypothesized that cocoa flavanol (CF) intake:
1. Will have little or no effect on indirect markers of NO production and exercise performance in healthy, well-trained, subjects
2. Will decrease exercise-induced oxidative stress and inflammation, leading to an improved recovery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical ethics committee UZ Brussel-VUB, 28/01/2015, ref: B.U.N. 143201523265

Study design

Randomized double-blind interventional placebo-controlled cross-over single-centre study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Community

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Exercise performance and recovery

Interventions
Participants perform an incremental cycling test on the first occasion. On two separate occasions, subjects perform two 30-min time trials on an indoor cycle-ergometer, interposed by passive rest, 1.5 and 3 hours after drinking a single dose of either:
1. Chocolate drink with high cocoa flavanol content (900 mg flavanols) (brandname: acticoa)
2. Placebo chocolate drink (13 mg flavanols)
The drinks are matched in caffeine, theobromine, calories, carbohydrates, fat and proteins.

Lactate, glucose, heart rate, rating of perceived exertion (RPE) and power output were measured during the time trials. Blood will be drawn at baseline and before and after each time trial and analyzed for several markers.

Intervention Type
Supplement

Primary outcome measure
1. Epicatechin serum concentration
2. Trolox equivalent antioxidative capacity (TEAC)
3. Uric acid (UA) plasma concentration
4. Malonaldehyde (MDA) plasma concentration
5. L-arginine/ADMA plasma concentration
6. Citrulline plasma concentration
7. Interleukin (IL)-1 plasma concentration
8. IL-6 plasma concentration
9. Tumor necrosis factor (TNF)-α plasma concentration
Measured at baseline and before and after each time trial (pre-TT1, post-TT1, pre-TT1, post-TT1) by HPLC, ELISA and spectrophotometry of plasma and serum (blood)

Secondary outcome measures

1. Time trial performance; time to complete a certain predefined workload during time trial 1 (90-120 min after cocoa intake) and during time trial 2 (210-240 min after cocoa intake)
2. Physiological parameters during time trial:
2.1. Lactate concentration, glucose concentration and rate of perceived exertion at start, after 10 min, after 20 min and at the end of each time trial
2.2. Heart rate and power output at start, after 5, 10, 15, 20, 25 mintues and at the end of each time trial

Overall study start date
01/03/2015

Completion date
01/07/2015

Eligibility

Key inclusion criteria
1. Age: between 20 years and 35 years
2. No severe head injuries in the past
3. No intake of neurological or psychological medication
4. Healthy
5. No hypertension
6. No cardiovascular disease
7. Cycling training of at least 10 hours per week for the last 2 years

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
15

Key exclusion criteria
1. Age: younger than 20 years or older than 35 years
2. Severe head injuries in the past
3. Intake of neurological or psychological medication which might alter cognitive function (psychotropic drugs, beta adrenergic blockers, steroids)
4. Hypertension
5. Cardiovascular disease
6. Other diseases which can alter cognitive function (diabetes, depression)

Date of first enrolment
15/03/2015

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
Belgium

Study participating centre
Vrije Universiteit Brussel
Belgium
1050

Sponsor information

Organisation
Vrije Universiteit Brussel

Sponsor details
Pleinlaan 2
Brussels
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Sponsor type
University/education

ROR
https://ror.org/006e5kg04

Funder(s)

Funder type
University/education

Funder Name
Vrije Universiteit Brussel

Results and Publications

Publication and dissemination plan
The data will be presented in a peer-reviewed journal.

Intention to publish date
01/12/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Lieselot Decroix.

IPD sharing plan summary
Available on request