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Study on the effects of cocoa flavanols on cognitive function in elderly subjects

Submission date
06/08/2014

Recruitment status
No longer recruiting

Registration date
12/08/2014

Overall study status
Completed

Last Edited
04/03/2015

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Human epidemiological studies suggest that an antioxidant called flavonoid may have beneficial effects on cognitive function (i.e. thinking, remembering, judging, and problem-solving) in elderly people. It is thought that one class of flavonoid, the flavanols, which are found in tea, grapes, red wine, apples and cocoa products may be able to prevent, to at least some degree, a decline in cognitive function. This study looks at the effect of drinking flavanol-rich cocoa drinks on the cognitive function in older people.

Who can participate?
Adults aged at least 60 with no evidence of a decline in cognitive function.

What does the study involve?
Participants are randomly allocated to one of three groups. Group 1 are given a cocoa drink containing 993 mg of cocoa flavanols. Group 2 are given a cocoa drink containing 520 mg of cocoa flavanols. Group 3 are given a cocoa drink containing 48 mg of cocoa flavanols.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in the trial. There are no risks in taking part in the trial either, as the products have been used in previous studies and are well-tolerated.

Where is the study run from?
A number of community centers in the L'Aquila district, central Italy.

When is the study starting and how long is it expected to run for?
December 2006 to July 2008.

Who is funding the study?
Mars Incorporated (USA)

Who is the main contact?
Giovambattista Desideri
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of the effects of short term (eight weeks) flavanol-rich product consumption on cognitive function in elderly subjects: Cocoa, Cognition and Aging (CoCoA) Study

Study objectives
The CocoA study was designed to test the hypothesis that the regular dietary inclusion of a beverage containing cocoa flavanols would be effective in improving cognitive performance in elderly subjects with no evidence of cognitive dysfunction

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Public Health Agency of L'Aquila (Italy), 07/12/2005, ref. 35/2005.

Study design
Single-center double-blind randomized controlled parallel-arm study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Age-related changes of cognitive performance

Interventions
Participants were randomized to consume daily for 8 weeks a drink containing 993 mg, 520 mg or 48 mg of cocoa flavanols

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Main outcome measures examined were changes in cognitive function following 8 weeks of regular cocoa flavanol consumption. Cognitive testing was performed using a combination of four well validated standardized tests: Mini Mental State Examination, Trail Making Test A and B and verbal fluency test. As predefined procedure, an integrated measure of overall cognitive function - composite cognitive z-score - was also constructed for each participant

Secondary outcome measures
Secondary outcome measures examined included:
1. Changes in blood pressure
2. Metabolic parameters
3. Plasma isoprostanes and markers of lipid peroxidation
These were assessed at 8 week together with neuropsychological evaluation

Overall study start date
04/12/2006

Completion date
30/07/2008

Eligibility

Key inclusion criteria

Subjects aged 60 years or more who reported themselves as unconcerned about their own memory functions and having no clinically significant co-existing medical conditions.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
90 individuals randomized to three dietary interventions with a ratio 1:1:1

Key exclusion criteria
1. Clinically significant co-existing medical conditions, including:
1.1. Known cardiovascular disease
1.2. Cerebrovascular events
1.3. Obesity or weight change ±10% body weight within the last 6 months before entering
1.4. Thyroid disorders
1.5. Inflammatory diseases
1.6. Neurological disorders
1.7. Dementia
1.8. Depression
2. Current smokers
3. Habitual users of antioxidant supplements
4. Habitual consumers of chocolate or other cocoa products
5. Individuals prescribed medications known to have antioxidant properties or to interfere with cognitive functions

Date of first enrolment
04/12/2006

Date of final enrolment
30/07/2008

Locations

Countries of recruitment
Italy

Study participating centre
Viale S. Salvatore, delta 6 Medicina
Coppito - L'Aquila
Italy
67100

Sponsor information

Organisation
Mars, Incorporated (USA)

Sponsor details
6885 Elm Street
McLean
United States of America
22101

Sponsor type
Industry

ROR
https://ror.org/028vrr082

Funder(s)

Funder type
Industry

Funder Name
Mars

Alternative Name(s)
Mars Incorporated, Mars, Incorporated

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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	01/03/2015		Yes	No