

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

Submission date 06/08/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/08/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 04/03/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

giovambattista.desideri@cc.univaq.it

Contact information

Type(s)

Scientific

Contact name

Prof Giovambattista Desideri

Contact details

Viale S. Salvatore, delta 6 Medicina

Coppito - L'Aquila

Italy

67100

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giovambattista.desideri@cc.univaq.it

Additional identifiers

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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 $\pm 10\%$ 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)

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

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