ISRCTN89815519 https://doi.org/10.1186/ISRCTN89815519

Bioavailability of dietary antioxidants in volunteers

Submission date
25/02/2015

Recruitment status
No longer recruiting

Registration date
05/03/2015

Overall study status
Completed

Last Edited
25/04/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
It is now well established that consumption of specific foods and food ingredients can be associated with considerable health benefits. The potential effect of dietary modifications can be enormous in managing such major public health problems as obesity, diabetes, cardiovascular disease and cancer. Nevertheless, it is clear that appropriately designed functional foods need to be developed first. The aim of the study is to find out more about the bioavailability of health-promoting food components. Bioavailability is defined as the ease with which nutrients are freed from the food and absorbed from the digestive tract to be incorporated into the human body.

Who can participate?
Adult healthy volunteers, subject to medical examination and inclusion/exclusion criteria.

What does the study involve?
This research project will evaluate nutrikinetics and comparative bioavailability of a range of dietary supplements comprising carotenoids, resveratrol, flavanols, omega 3 fatty acids etc as well as their combinations at different doses in different food matrices, such as chocolate, butter and vegetable oils. Quantitative parameters will be assessed in the postprandial period (after meals) at different time points over the 8-week period of continuous consumption of supplemented foods. The selected functional foods will be added to the participants' normal diet in limited amounts, practically excluding any possibility of adverse effects. Blood sample collection for evaluating nutrikinetics/bioavailability of dietary supplements will be the only minimally invasive procedure used in this study. Non-invasively collected samples of exfoliated corneocytes and sebaceous gland secretions from the surface of facial skin as well as cerumen (ear-wax) and tear fluid samples will also be used for assessing physiological effects of the dietary supplements.

What are the possible benefits and risks of participating?
There could be some benefits associated with the consumption of health-promoting dietary supplements but they are likely to be minor since the study only lasts 8 weeks. Participation will not be associated with any risks.

Where is the study run from?
Lycotec (UK)

When is the study starting and how long is it expected to run for?
April 2015 to March 2016

Who is funding the study?
Lycotec (UK)

Who is the main contact?
Dr Yvan Petyaev

Contact information

Type(s)
Scientific

Contact name
Dr Ivan Petyaev

Contact details
Lycotec Ltd, Unit 3A, McClintock Building
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Bioavailability and physiological effects of dietary antioxidants of different functional foods and beverages in volunteers

Study objectives
Consumption of specific foods and food ingredients can be associated with considerable health benefits. However, there are uncertainties with regard to the bioavailability of potentially beneficial food ingredients.
This study primarily addresses questions related to the bioavailability of health-promoting dietary supplements comprising carotenoids, resveratrol, flavanols, omega 3 fatty acids etc as

well as their combinations at different doses in different food matrices, such as chocolate, butter and vegetable oils. We expect that this study will eventually help in developing new functional foods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
This study is designed to investigate the nutrikinetics and comparative bioavailability of different products containing carotenoids, flavanols, resveratrol, 3-omega fatty acids and their combinations. These products will be present at different doses in different food matrices, such as chocolate, butter and vegetable oils given to healthy volunteers in order to evaluate nutrikinetics and comparative bioavailability of the nutrients of interest. Although mild effects of dietary supplements may take place, the study can be regarded as observational.

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Bioavailability and physiological effects of nutrients in healthy subjects

Interventions
This observational study will include dietary supplementation. Therefore study subjects will be allocated to twelve different dietary supplementation groups (30 subjects per group).
Product formulations used in the study groups will include lycopene, lutein and resveratrol combined with either of the following food matrices: flavanol-containing 85% dark chocolate, dairy butter or flaxseed oil containing 3-omega fatty acids. Daily intake of Lycopene and Lutein will constitute 7mg (per 8g of chocolate, 30 g of dairy butter or 30ml of flaxseed oil). Daily intake of Resveratrol will constitute 120mg (per 8 g of chocolate, 30 g of dairy butter or 30ml of flaxseed oil).
The following groups (30 subjects in each) will be included:
1. Lycopene + chocolate
2. Lutein + chocolate
3. Resveratrol + chocolate
4. Lycopene + butter

5. Lutein + butter
6. Resveratrol + butter
7. Lycopene + oil
8. Lutein + oil
9. Resveratrol + oil
10. Chocolate (control)
11. Butter (control)
12. Oil (control)

Intervention Type
Supplement

Primary outcome measure
The principal objective of this research project is to assess bioavailability of a range of dietary supplements comprising carotenoids, flavanols, resveratrol, omega 3 fatty acids etc as well as their combinations in different food matrices, such as chocolate, butter and vegetable oils. Results on supplement bioavailability will constitute primary outcome measures which will be based upon analysing blood samples obtained at day 1 (postprandial) and following weeks 1, 2, 3, 4, 6, and 8 of the trial. All these results will be compared to individual pre-trial results (time point 0).

Secondary outcome measures
1. Comparative bioavailability assessment of the same group of dietary supplements comprising carotenoids, flavanols, resveratrol, omega 3 fatty acids etc as well as their combinations at different doses in different food matrices, such as chocolate, butter and vegetable oils
2. Assessment of dietary supplement effects on the characteristics of the facial skin of trial participants
3. Assessment of dietary supplement effects on the characteristics of the cerumen (ear wax) of trial participants
4. Assessment of dietary supplement effects on the lipid association with conjunctival epithelium cells in the tear fluid of trial participants

These secondary outcome measures will be determined by comparing results obtained for samples collected before trial (time point 0) with the final time point of the study (following 8 weeks of food supplement consumption).

Overall study start date
01/04/2015

Completion date
31/03/2016

Eligibility

Key inclusion criteria
1. All study participants should be healthy Caucasian males and females, age 20–80
2. Female subjects of childbearing potential should agree to undergo pregnancy tests and to use an appropriate method of contraception (i.e. oral contraceptive steroids, intrauterine device, barrier method)
3. All study participants should have findings within the normal range in medical history, physical examination, and relevant laboratory tests

4. All study participants should agree to undergo a pre-study physical examination and laboratory investigations
5. All study participants should be able to comprehend and willing to sign both statements of informed consent (for screening and phase-related procedures)
6. Only non-smokers or mild to moderate smokers (less than 10 cigarettes per day) should be enrolled in the study

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
360

Key exclusion criteria
The exclusion criteria (subjects who meet any of the following criteria are to be excluded from participating in the study):
1. The presence of a psychiatric disorder, antagonistic personality, poor motivation, emotional or intellectual problems likely to limit the validity of consent to participate in the study or limit the ability to comply with protocol requirements
2. History of or current compulsive alcohol abuse (> 10 drinks weekly), or regular exposure to other substances of abuse
3. Participation in another study with an experimental drug within 4 weeks before the initiation of the proposed dietary study
4. A major illness within 3 months before commencement of the screening period
5. History of hypersensitivity to food ingredients
6. History of bronchial asthma
7. Donation or loss of blood equal to or exceeding 500 ml during the 8 weeks before the initiation of the proposed dietary study or donation or loss blood from 250 to 500 ml in the 6 weeks before the initiation of the proposed dietary study or donation or loss of blood up to 250 ml in the 4 weeks before the initiation of the proposed dietary study
8. Resting heart rate of over 100 beats per minute or below 45 beats per minute during the screening period, either supine or standing
9. Positive testing for HIV or hepatitis B antigens
10. History of epilepsy
11. Difficulty fasting or consuming the standard meals
12. Subjects who do not tolerate venipuncture
13. Subjects on a special diet (e. g. liquid, protein, raw food diet) within 4 weeks before the initiation of the proposed dietary study
14. Drug addiction requiring treatment in the past 12 months
15. Subjects who do not agree to fully participate in wash-out period and exclude from the diet the recommended food for 4 weeks before the initiation of the study and during the study

Date of first enrolment
01/04/2015

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lycotec Ltd
Unit 3A, McClintock Building
Granta Park
Cambridge
United Kingdom
CB21 6GP

Sponsor information

Organisation
Lycotec Ltd

Sponsor details
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Sponsor type
Industry

Website
http://www.lycotec.com/

ROR
https://ror.org/032951a18

Funder(s)

Funder type
Industry

Funder Name
Lycotec Ltd

Results and Publications

Publication and dissemination plan
Publications in scientific journals and conference presentations. If trial initiation is not delayed, first papers are likely to be submitted by July 2016.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2018		Yes	No
Other publications	Lycopene presence in facial skin corneocytes and sebum and its association with circulating lycopene isomer profile: Effects of age and dietary supplementation	13/03/2019	25/04/2023	Yes	No
Other publications	Pharmacokinetics and Oxidation Parameters in Volunteers Supplemented with Microencapsulated Docosahexaenoic Acid	01/07/2018	25/04/2023	Yes	No