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ProFiLE human bioavailability trial: Lutein bioavailability from a lutein-fortified sports beverage and a lutein-fortified cupcake

Submission date
15/05/2025

Recruitment status
No longer recruiting

Registration date
11/08/2025

Overall study status
Completed

Last Edited
11/08/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The Nutrition Research Centre Ireland (NRCI), based at the Southeast Technological University (SETU), is presently engaged in investigating the potential of lutein-enriched functional foods to effectively introduce lutein into the human body. This investigation was carried out by the NRCI through a bioavailability study in collaboration with Cybercolors Ltd (Fermoy, Ireland). Lutein is a micronutrient naturally found in various fruits and vegetables. It is a vital component of a balanced diet and has been scientifically proven to enhance both visual and cognitive function, with positive benefits for age-related macular degeneration (AMD), the world's leading cause of blindness. The human body cannot produce lutein on its own, and so it must be obtained through nutrition. This is achieved by incorporating foods such as dark leafy greens and egg yolks into one's diet or by opting for dietary supplements. Recent findings indicate that the daily intake of lutein often falls short of providing the related health benefits. This confirms the huge potential for lutein fortification in functional foods. The research team have developed two functional food products fortified with lutein to support human nutrition. These food products are a sports isotonic beverage and cupcakes. This study aims to evaluate the effectiveness of lutein-fortified foods as a method to deliver lutein directly into the human body, through a bioavailability study. The study involves measuring lutein levels in the blood at different time points before and after participants eat a single serving of the lutein-fortified isotonic beverage (500 ml) or cupcake (50g).

Who can participate?
Healthy volunteers between 18-65 years of age, who were a non-smoker, non-pregnant, had no allergies i.e., gluten, eggs, dairy, no chronic disease (e.g., diabetes, cardiovascular diseases, Alzheimer's disease, etc.), and not currently taking medication or supplements that could potentially interfere with lutein absorption.

What does the study involve?
The study spanned over five days, commencing with a 10-hour session on Day 1, held at the NRCI. Each participant was asked to consume one single serving of either the lutein fortified sport isotonic beverage or the lutein fortified cupcake. After consumption, a qualified

phlebotomist withdrew blood from each participant at regular intervals throughout the day. Days 2, 3, 4 and 5 entailed one brief daily visit (15-20 minutes) to the NRCI, where a single blood sample was drawn each day. The first blood sample of each day is a fasting blood sample.

What are the possible benefits and risks of participating?
Benefits for participants are a voucher with €250 spendable in retailers. In addition, the participants could know the levels of lutein in their blood, and their overall carotenoid content at tissue level (skin carotenoid measurement).
The consumption of the lutein-enriched foods is expected to be free of side effects, as participants were pre-screened to confirm the absence of any allergies. All food products used in this trial were fully compliant with all EU food safety regulations and standards and were safe to consume.
However, it's important to note that while uncommon, the blood withdrawal procedures might carry a slight risk of side effects, including bruising, pain, bleeding, fainting, and/or dizziness.
Where is the study run from?

When is the study starting and how long is it expected to run for?
February 2024 to March 2024

Who is funding the study?
Cybercolors Ltd

Who is the main contact?
Dr Alfonso Prado-Cabrero, aprado-cabrero@wit.ie

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
ProFiLE human bioavailability trial: Lutein bioavailability from a lutein-fortified sports beverage and a lutein-fortified cupcake

Acronym
ProFiLE

Study objectives
Lutein is a naturally occurring carotenoid and colour pigment that is considered an antioxidant and anti-inflammatory bioactive that protects the retina and contributes to brain health. Lutein is commonly found in dark green leafy vegetables such as spinach and kale, and in fruits such as oranges and papayas. Due to the low consumption of such foods among the general population, lutein is not consumed in adequate amounts to reap its health benefits. Individuals with age-related macular degeneration (AMD) and people aiming to improve their vision and cognition consume lutein through capsules. However, children and many elderly people have swallowing difficulties. Therefore, it is desirable to develop alternative methods to increase lutein intake among the population. Functional foods offer this opportunity, as they include added bioactives among their ingredients. This human bioavailability study aimed to test the capacity of two lutein-fortified foods prepared by our group to increase the levels of lutein in the bloodstream of human participants.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 27/02/2024, South East Technological University (SETU) Research Ethics Committee (Main Campus Cork Road, Waterford, X91 KOEK, Ireland; +353(0)51302000; Ethics.wd@setu.ie), ref: SETU/REC/23/24/001

Study design
Single-centre interventional randomized single-dose 96-hour bioavailability human trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Laboratory

Study type(s)
Screening

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Healthy individuals

Interventions
Random allocation sequencing was performed by the study statistician. Participants were randomly allocated to two active intervention groups, and a 5% level of significance was chosen (i.e. 95% confidence level). Participants were randomly allocated into one of the two groups:

Group 1 (10 people) consumed 500 mL of a sports beverage that has been fortified with an emulsion of the carotenoid lutein (~10 mg lutein).

Group 2 (9 people) consumed one 50-g cupcake that had been fortified with an emulsion of lutein (~10 mg lutein).

The study spanned over five days, commencing with a 10-hour session on Day 1. Each participant was asked to consume one single serving of either the lutein fortified sport isotonic beverage or the lutein fortified cupcake. After consumption, a qualified phlebotomist withdrew blood from each participant at regular intervals throughout the day. Days 2, 3, 4 and 5 entailed one brief daily visit (15-20 minutes) to the study centre, where a single blood sample was drawn each day. The first blood sample of each day is a fasting blood sample.

Intervention Type
Supplement

Primary outcome measure
Lutein is measured using high-performance liquid chromatography with diode array detection (HPLC-DAD) at baseline, and 3, 6, 10, 24, 48, 72 and 96 hours after taking the lutein-fortified food

Secondary outcome measures

There are no secondary outcome measures

Overall study start date
27/02/2024

Completion date
27/03/2024

Eligibility

Key inclusion criteria
1. Healthy adults, defined as currently/historically not having a chronic disease, having no history of gastrointestinal diseases that could inhibit lutein absorption, having no current severe illnesses or infections, and having not undergone major surgery within the last 6 months
2. Aged between 18 and 65 years old
3. No food allergies
4. Not taking any medications or dietary supplements that would interfere with lutein absorption

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
20

Total final enrolment
19

Key exclusion criteria
1. Pregnant or lactating women
2. Participants taking medications or supplements known to impact lutein absorption
3. Individuals with allergies to gluten, eggs, and dairy were excluded from the study as the intervention required participants to ingest lutein-fortified foods containing gluten (flour), eggs, and dairy ingredients (butter)

Date of first enrolment
01/03/2024

Date of final enrolment

27/03/2024

Locations

Countries of recruitment
Ireland

Study participating centre
Nutrirtion Research Centre reland
Carriganore House, SETU West Campus, Carriganore
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Sponsor information

Organisation
South East Technological University

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Sponsor type
University/education

Website
https://www.setu.ie

ROR
https://ror.org/03fgx6868

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journal.

Intention to publish date
15/07/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available (private funding).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			27/05/2025	No	Yes