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Perspective of different forms of essential amino acid supplements and effects on appetite in older men and women

Submission date
23/06/2016

Recruitment status
No longer recruiting

Registration date
01/07/2016

Overall study status
Completed

Last Edited
17/12/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The purpose of the study is to understand the preferences of elderly people when taking nutritional supplements rich in essential amino acids in different forms, and to see how these supplements affect their appetite. Through finding this out the researchers hope to ensure beneficial supplements can be designed in a form people will like. The study involves two experiments to investigate the effects of these supplements on appetite measures in the form of a nutritional Bar and Gel.

Who can participate?
Healthy volunteers aged between 60-80 years old.

What does the study involve?
There are two arms to the study. Each participant can choose whether to take part in both arms or just one. If they choose to take part in one arm, they can also decide which arm they wish to take part in. For arm 1, each participant attends the trial participating centre on three separate days. On each day, they take one of three tests. They do all three tests, on separate days, in a random order. The first test involves eating a nutritional bar rich in essential amino acids and then resting an hour before eating a breakfast of porridge. The second test involves eating a nutritional gel rich in essential amino acids and testing an hour before eating a breakfast of porridge. The third test involves not taking any nutritional supplements and just eating the porridge. All participants give blood samples throughout the tests and are asked to fill in questionnaires in the hour between eating the supplements and having breakfast. For arm 2, the participants again attend three sessions in a random order and eat nutritional supplements and /or breakfast as before. However, this time, those participants taking the supplements eat the breakfast at the same time, rather than waiting an hour and no blood samples are taken.

What are the possible benefits and risks of participating?
It is unlikely that participants will experience any long-term physiological benefits from taking part in this study. Blood samples will be taken by trained researchers using aseptic techniques and in accordance with local and national guidelines to minimise any risks.. Blood sample

preparation will be separated from the testing area and participants to prevent cross-contamination and reduce the potential of any accidents. Deterioration of kidney function as result of eating a lot of protein can happen over a number of years, however only if the person already has kidney problems.. Due to the acute nature of the supplementation in this study even if a person is suffering from kidney problems the risk of making it worse by taking part in this study is very small.

Where is the study run from?
Leeds Beckett University (Carnegie Research Institute) and Higher Education Innovation Funding (HEIF) has been secured for this study.

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

Who is funding the study?
1. Leeds Beckett University
2. Higher Education Innovation Funding (HEIF)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
The impact of essential amino acid supplements enriched with L-leucine on appetite and energy intake in elderly: a randomised, crossover trial

Study objectives
It is expected that essential amino acid based nutritional supplements enriched with L-leucine will not compromise appetite and energy intake in healthy elderly people.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds Beckett Local Research Ethics Committee, 18/02/2015

Study design
Randomised, crossover trial design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Nutritional supplements

Interventions
There are two arms to the study. Each participant can choose whether to take part in both arms or just one. If they choose to take part in one arm, they can also decide which arm they wish to take part in.

Arm 1:
Each participant attends the trial participating centre on three separate days. on each day, they take one of three tests. They do all three tests, on separate days, in a random order. These tests are:
1. Consuming an essential amino acids based nutritional bar enriched with L-leucine: oral administration of a 37.5 g nutrition bar (134.5 kcal) containing 7.5 g of essential amino acids (40% L-Leucine)
2. Consuming an essential amino acids based nutritional gel enriched with L-leucine: oral

administration of a 50 ml nutrition gel (113.9 kcal) containing 7.5 g of essential amino acids (40% L-Leucine)
3. No consumption of an essential amino acids based supplement

All participants then wait for an hour before consuming an ad-lib breakfast (standardised breakfast of porridge). During this hour, they are asked to complete questionnaires on hunger and opinion of the supplement consumed (if any).

At the start of each of the three sessions, a phlebotomist inserts a cannulla into a vein of each participant. Blood samples are taken at a number of occasions throughout the testing session for later hormonal response analysis.

Arm 2:
This arm of the study is very similar to arm 1. There are again three tests that all participants take part in over three days in a random order. These tests are almost identical to those of arm 1. However, this time the ad lib breakfast is eaten at the same time as the amino acid supplements are consumed (if any). Participants are also not required to give any blood samples.

Intervention Type
Supplement

Primary outcome measure
Arm 1:
1. Composite appetite ratings using visual analogue scales, taken at baseline immediately post-consumption and every 15 min until post consumption of the ad lib breakfast
2. Energy intake, measured via the quantity of breakfast consumed

Arm 2:
Composite appetite ratings using visual analogue scales before and after the ad lib breakfast

Secondary outcome measures
Arm 1:
1. Gut hormone concentrations from blood samples, via plate reader and ELISA. Measurements to be taken at baseline immediately post-consumption and every 30 min until the ad lib breakfast
2. Plasma concentration of essential amino acids from blood samples, via gas chromatography mass spectrometry. Measurements to be taken at baseline immediately post-consumption and every 30 min until the ad lib breakfast
3. Palatability, measured using visual analogue scales. Measurements to be taken at baseline immediately post-consumption and every 15 min until post consumption of the ad lib breakfast

Arm 2:
Palatability, measured using visual analogue scales before and after the ad lib breakfast

Overall study start date
01/01/2015

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1. Male and female adults aged between 60 and 80
2. Free from vascular and metabolic disease

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
10

Total final enrolment
11

Key exclusion criteria
1. Smoking
2. Use of oestrogens within the previous three months
3. Lactose intolerant

Date of first enrolment
01/07/2015

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Carnegie Faculty, Leeds Beckett University
Room 211 Fairfax Hall
Headingley Campus
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Sponsor information

Organisation
Leeds Beckett University

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Sponsor type
University/education

ROR
https://ror.org/02xsh5r57

Funder(s)

Funder type
Research council

Funder Name
Higher Education Innovation Funding (HEIF)

Funder Name
Leeds Beckett University

Alternative Name(s)
Leeds Beckett

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. Preliminary results ESPEN September 2016
2. Publication November 2016 (One article on females, and a case study article on men)

Intention to publish date

30/11/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		30/06/2016	13/07/2016	No	Yes
Results article	results	28/11/2017	17/12/2019	Yes	No