

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	☐ Prospectively registered ☐ Protocol ☐ Statistical analysis plan ☒ Results ☐ Individual participant data
Registration date 01/07/2016	Overall study status Completed	
Last Edited 17/12/2019	Condition category Nutritional, Metabolic, Endocrine	

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

Protocol serial number

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

Study type(s)

Treatment

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 cannula 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Total final enrolment

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**

United Kingdom

England

Study participating centre

Carnegie Faculty, Leeds Beckett University

Room 211 Fairfax Hall

Headingley Campus

Leeds

United Kingdom

LS6 3QS

Sponsor information**Organisation**

Leeds Beckett University

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

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?
Results article	results	28/11/2017	17/12/2019	Yes	No
Participant information sheet		30/06/2016	13/07/2016	No	Yes