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Growth of skeletal muscle in response to feeding specific amino acids

Submission date	Recruitment status	[_] Prospectively registered
14/09/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/12/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2019	Other	

Plain English summary of protocol

Background and study aims
Resistance exercise involves using an external force (such as heavy weights) to cause the muscles to contract. Eating or drinking protein after resistance exercise stimulates the making of new muscle proteins (muscle protein synthesis). Branched chain amino acids (BCAA) are often suggested as the main part of protein responsible for the increased protein synthesis, but no study has directly examined this. The aim of this study is to find out whether consuming BCAA increases muscle protein synthesis after resistance exercise in trained, young adult males.

Who can participate?
Healthy men aged 18-45 who are experienced weight lifters

What does the study involve?
This study consists of two phases. For each phase, participants undertake two 8-hour studies at the School of Sport and Exercise Sciences at the University of Birmingham. Before the studies, participants' body composition and the maximum weight they can lift with one leg are assessed. Participants complete an intense bout of resistance exercise. Following the exercise, in Phase I participants are randomly allocated to consume either a drink containing BCAA or a placebo (dummy) drink. In Phase II, participants are randomly allocated to consume either a carbohydrate drink or a drink containing both BCAA and carbohydrates. Muscle samples (biopsies) are collected from the quadriceps (thigh) and blood samples are taken from a hand vein to work out the rates of protein synthesis.

What are the possible benefits and risks of participating?
Participants will receive information about how their muscle changes after exercise. Participants may experience discomfort during the blood or tissue sampling.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
October 2009 to October 2011

Who is funding the study?
GlaxoSmithKline Nutritional Healthcare (UK)

Who is the main contact?
Dr Sarah Jackman

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Branched-chain amino acid ingestion stimulates muscle myofibrillar protein synthesis following resistance exercise in humans

Study objectives
Ingestion of only branched-chain amino acids (BCAA) will be sufficient for the stimulation of myofibrillar muscle protein synthesis (MPS) rates after resistance exercise in a fed state in trained, young adult males.

Ethics approval required

Old ethics approval format

Ethics approval(s)
National Research Ethics Service ethics board, 24/09/2009, ref: 09/H1211/77

Study design
Crossover double-blind intervention study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

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
Resistance exercise

Interventions
This research project was performed in two phases. The design, all procedures, risks and analyses of each phase were the same between the two phases. The only difference was the substances that were ingested. For each phase, 10 healthy, weight trained males aged 18 - 45 (from gyms in the local area) undertook two ~8 hour trials that took place in the School of Sport and Exercise Sciences at the University of Birmingham. Prior to the experimental trials, the maximum weight that could be lifted with one leg and body composition were assessed. During the experimental trials, participants were infused with metabolic tracers, muscle biopsies were collected and blood samples taken to determine rates of protein synthesis. Each participant completed an intense bout of resistance exercise followed by three muscle biopsies. Muscle and blood samples were analyzed to determine the rates of muscle protein synthesis and the signalling mechanisms inside the muscle that lead to increased synthesis. Following the exercise, participants will be randomised to consume either a BCAA-containing solution or a placebo in Phase I. In Phase II, a carbohydrate control solution will be compared to BCAA plus carbohydrates. Thus, in each phase, the BCAA will be compared with the appropriate control.

Intervention Type
Supplement

Primary outcome measure
Fractional synthetic rate (FSR), measured using gas combustion isotope ratio chromatography mass spectrometry (GCCIRMS) over the 4h period following drink ingestion.

Secondary outcome measures

1. Signalling proteins, measured using western blots
2. Amino acids in blood, measured using gas chromatography mass spectrometry (GCMS)
3. Tracers enrichment in muscle, measured using GCMS
4. Tracers enrichment in plasma, measured using GCMS
5. Insulin in serum, measured using enzyme-linked immunosorbent assay (ELISA)
6. Glucose in plasma, measured using automated analysers

Blood sample timepoints: -240, -145, -85, -25, 0, 15, 30, 45, 60, 75, 90, 120, 150, 180, 240 min
Muscle biopsy timepoints: 0, 60 and 240 min

Overall study start date
01/10/2009

Completion date
01/10/2011

Eligibility

Key inclusion criteria
1. Male, aged 18-45 years
2. Healthy (no known metabolic disorder)
3. Experienced weight lifter for more than 6 months (at least 2 leg resistance training sessions per week)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Male

Target number of participants
20

Total final enrolment
10

Key exclusion criteria
Not simultaneously taking part in another scientific/clinical study

Date of first enrolment
01/10/2009

Date of final enrolment
01/05/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
GlaxoSmithKline Nutritional Healthcare

Sponsor details
GSK House, 980 Great West Road
Brentford, Middlesex
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Sponsor type
Industry

ROR
https://ror.org/01xsqw823

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline Nutritional Healthcare

Results and Publications

Publication and dissemination plan
The results of the study will be disseminated to the scientific community via publication in scientific journals (that will ideally be open access). Ideally, the results of the study will also be presented at scientific conferences. Furthermore, it is hoped that the results of the study will be disseminated to the public in a lay summary via various media outlets, and also individual data will be made available and communicated to study volunteers upon request.

Intention to publish date
24/01/2017

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are available from Dr Sarah Jackman on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/06/2017	31/10/2019	Yes	No
HRA research summary			28/06/2023	No	No