The influence of gravity and body orientation on protein digestion and absorption.

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From Page 14 of the C1 research protocol document:Primary Objective: To determine if changes in gravity through alterations in post-prandial body position affects protein digestion and absorptionSecondary objectives: To determine if changes in…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malabsorption conditions
Study type	Interventional

Summary

ID

NL-OMON41945

Source
ToetsingOnline

Brief title
Body position and dietary protein

Condition

- Malabsorption conditions

Synonym
Digestion, Protein

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Digestion, Gravity, Protein

Outcome measures

Primary outcome

From Page 9 of the C1 research protocol document:

Primary endpoints are the temporal patterns of plasma concentrations of amino

acids, glucose, insulin and paracetamol (to determine gastric emptying).

Secondary outcome

From Page 9 of the C1 research protocol document:

Secondary study parameters are blood pressure and heart rate.

Study description

Background summary

From Page 12-13 of the C1 research protocol document:

The regulation of skeletal muscle mass is dependent on the long-term balance of protein turnover, comprised of the ongoing processes of protein synthesis and protein breakdown. Improvements in protein balance and/or higher muscle protein synthesis rates have been reported following the ingestion of various types of dietary protein: whey protein (16), casein protein (16), soy protein (18), casein protein hydrolysate (11, 15), egg protein (13), and whole milk and/or fat-free milk (5, 22). Milk protein and its main isolated constituents, whey and casein, are the most widely studied dietary proteins. Casein and whey protein seem to have distinct anabolic properties, which are attributed to differences in digestion and absorption kinetics (2-4, 11). Whereas whey protein is a soluble protein that leads to rapid intestinal absorption, intact casein clots in the stomach delaying its digestion and absorption and the subsequent release of amino acids in the circulation (7). The fast, but transient rise in plasma amino acid concentration after whey protein ingestion

can lead to higher protein synthesis and oxidation rates (2, 3, 18). Thus, it is strongly suggested that the rapidness of protein digestion and absorption is a primary factor determining the extent to which muscle protein synthesis can be stimulated.

We have previously demonstrated that dietary protein is digested and absorbed during an acute period of overnight rest (9). However, the protein digestion kinetics appeared to be somewhat altered when compared to similar data collected from our previous work conducted during the daytime. We speculated that digestion might somehow be modulated if the post-prandial or digestive phase occurs while lying in a horizontal body position as experienced during overnight sleep. To gather a further understanding of protein digestion during the night, we feel it necessary to isolate and study how body position, and ultimately the acting effect of gravity, affects protein digestion and the stimulation of muscle protein synthesis.

Alterations in the acting effect of gravity on absorption of orally administered pharmaceuticals has previously been demonstrated during simulated microgravity environment (-6° head tilt) (10). Results from the aforementioned study demonstrate that absorption of the pharmacological agent occurred at a more rapid rate suggesting that gastric function may actually improve when the effect of gravity is altered. However, no data pertaining to changes in protein digestion and stimulation of muscle protein synthesis under modified effects of gravity (i.e., lying horizontally vs. sitting vertically) currently exist.

The concept of altered protein digestion and absorption and the resultant stimulatory effect on skeletal muscle protein synthesis caused by altered effects of gravity is currently understudied. The present study is designed to detect if there is a clear interaction of post-prandial body position on gastric emptying and the digestion and absorption of dietary protein.

Study objective

From Page 14 of the C1 research protocol document:

Primary Objective: To determine if changes in gravity through alterations in post-prandial body position affects protein digestion and absorption

Secondary objectives: To determine if changes in gravity through alterations in post-prandial body position affects protein digestion and absorption and if such effects can be explained by delayed gastric emptying.

Hypotheses: We hypothesize that horizontal body positioning will cause a decreased and delayed peak plasma amino acid concentration after ingestion of dietary protein. Lastly, we hypothesize that the inefficient absorption of amino acids into blood plasma will be explained by impairments in gastric

emptying.

Study design

From Page 16-18 of the C1 research protocol document:

The study design of this randomized, placebo-controlled crossover test is depicted in Figure 1. After the subjects arrive at the University, we will check if they meet all the prerequisites described in section 3.2 and ask them to put on comfortable clothing. A catheter will be inserted into one of the antecubital veins for continuous blood collection. A basal blood sample (10ml, t= -30) and resting blood pressure and heart rate will be collected. After these measurements are taken during the inversion test, subjects will then lay on the tiltable bed and will be slowly reclined and secured at a body position of 0° (horizontal), measured with an electronic level. After an acclimation period of 30 minutes, a blood sample will be collected (10ml, t= 0) and blood pressure and heart rate will be measured at the upper arm and at the lower leg. The protein drink will then be an ingested through a drinking straw and the post-prandial period will begin. Further blood sampling will occur at t = 15, 30, 45, 60, 90, 120, 180, and 240 min and blood pressure and heart rate will be collected from the upper arm and from the lower leg at t = 60, 120, 180 and 240 min. The subjects will be slowly returned to an upright body position following the collection of the last blood sample. The exact same sampling protocol will be followed on the upright test-day except that subjects will remain in a seated, vertical body position for the duration of the experiment.

Intervention

The main intervention is a manipulation of the effects of gravity on protein digestion by studying the post-prandial phase in non-upright body positions.

On one test, subjects will lay horizontally at 0deg for 4.5h. On the other test day, subjects will remain upright (vertical) in a seated position.

Study burden and risks

From Pages 10-11 of the C1 research protocol document:

The burden and risks associated with participation in the pilot test is low. Insertion of the catheters is comparable to a blood draw and could result in a small hematoma. Blood will be sampled 10 times (10 mL) during each test. The total amount of blood drawn (100mL each test) is minimal when compared to the amount taken in a single blood donation (500m) and will be completely restored within 1 month. Each participant will come to the laboratory once for the orientation visit (1 hour and twice for the tests (~6 hours each). Before initiating an orientation visit, interested subjects will be asked questions to

ensure they are not lactose intolerant or display any other gastrointestinal disorders and fill in and return a medical questionnaire. During the orientation visit, medical questionnaires will be checked and signed and the informed consent form will also be filled in. Before starting each test day, subjects will need to be fasted and will be asked to refrain from eating or drinking (except for water) from 22h00 the evening before. Subjects will also refrain from physical activity or alcohol consumption. Participants will consume a milk-based protein beverage (commercially available food product) once during each test while the researchers will collect blood samples. Blood pressure and heart rate will be measured each hour. There is no direct benefit for the participants except for their contribution to the scientific knowledge of physiology and nutritional strategies that may aid in preventing muscle loss in clinical and microgravity situations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Healthy males
• Age between 18 and 35 y
• BMI between 18.5 and 30 kg/m2

Exclusion criteria

• Celiac disease
• Lactose intolerance
• Smoking
• Diabetes
• Cancer
• Donated blood within the last 3 months
• Diagnosed GI tract diseases
• Any medications known to affect digestion and absorption (i.e. proton pump inhibitors, bicarbonate tablets, non-steroidal anti-inflammatories).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2015
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	12-02-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26539
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51216.068.14
OMON	NL-OMON26539