Effect of arachidonic acid supplementation on skeletal muscle

PARTICIPANT INFORMATION SHEET

We invite you to participate in a clinical trial on the effects of a dietary fat (arachidonic acid) supplementation on muscle protein synthesis and recovery from exercise. Your participation in the research is entirely voluntary (your choice). If you do agree to take part, you are free to withdraw from the research at any time, without having to give a reason.

Who can take part?

You can take part if you are a male, aged between 18-35 years of age, and have been resistance training your legs for at least 1 year. You must not be taking any performance enhancing drugs. You must be available for 4 visits which will take place at the Liggins Institute (Grafton).

Who designed the trial?

This trial was designed by research staff at the University of Auckland

Why might arachidonic acid have effects on muscle?

Arachidonic acid is an essential fat which is important in the body’s natural protective response to stress or injury. It has been suggested that arachidonic acid may augment the muscle response to exercise. This means you may be more sore than usual, but also experience bigger muscle growth.

What is the aim of the research?

The aim of the research is to assess the effects arachidonic acid supplementation on the ability of muscles to make new protein after exercise. The research will also examine if arachidonic acid supplementation changes the types of fats that are present in your muscle and blood. We will not be able to tell you if you were receiving arachidonic acid or placebo until several months after the end of the research.

What is the supplement being tested in the research?

The supplement is 1.5 g per day of arachidonic acid contained in sunflower oil. The placebo will be a corn-soy oil blend. You will be asked to consume four capsules per day for a total of four grams of the allocated oil daily for one month.

What happens if I decide to take part?

This research requires four visits.

Visit one (screening 1.5 hours)
You will arrive at the Liggins Institute, University of Auckland at 85 Park Road Grafton. We will use a DEXA scan to measure your bone density, muscle mass and percentage body fat. We will then use a pqCT machine to measure the size of your thigh muscle. After the scans a small area on your thigh will be ‘frozen’ and a muscle biopsy will be taken. Afterwards we will determine your maximal leg strength (1 repetition maximum) for leg press and knee extension using weight equipment, and maximum voluntary contraction of your thigh muscles using a Biodex machine.

**At home Supplementation (1 month)**

Between visit one and two we will provide you with a bottle containing enough supplement capsules for one month. We will ask you to take 4 capsules each day which will contain either arachidonic acid or a placebo. We will ask you to continue your normal training program and take the provided capsules daily for 1 month.

**Visit two (8 hours)**

You will arrive at the Liggins Institute at 85 Park Road Grafton. We ask that you do not eat anything after 10 pm the night before. You will undergo a DEXA scan and pqCT to determine muscle gain over the 1 month of supplementation and training. We will then insert a cannula in each arm and start an infusion of a stable isotope of an amino acid. This isotope is not radioactive and is treated by your body exactly the same as protein from food. You will rest for 2 hours and then undergo a muscle biopsy. After the resting biopsy you will complete 8 sets of leg extension and 8 sets of leg press at 80% of the heaviest load you can lift. You will then undergo 3 additional biopsies, taken immediately after exercise and 2 and 4 hours of recovery. We will also take small blood samples every half hour. Before you go home we will provide you with a meal.

**Visit Three (1 hour)**

24 hours after visit two you will arrive back at the Liggins Institute and undergo a blood test. We will also assess the extent of delayed onset muscle soreness (DOMS) from the exercise bout undertaken on visit two, and measure your recovery of muscle strength on the Biodex machine. We will also apply a rubber probe to your leg and apply pressure until you feel discomfort as a measure of your pain pressure threshold.

**Visit Four (1.5 hours)**

48 hours after visit two you will arrive back at the Liggins Institute and undergo a final muscle biopsy to determine how the exercise and supplementation affected the stem cells within your muscle. We will take another blood sample and assess the extent of muscle soreness from the exercise bout performed on visit two and measure your recovery of muscle strength on the Biodex once more. We will also apply a rubber probe to your leg and apply pressure until you feel discomfort as a measure of your pain pressure threshold.

**How many and what type of people will be in the research?**

There will be 20 healthy males between the ages of 18 and 35. They must have been resistance training their legs for at least 1 year.
The risk and benefits of the research

Overall there are no major risks associated with taking part in this research. During visits 1 and 2 there is low risk associated with the DEXA. We are exposed to very low amounts of radiation all the time from the sun and other sources in our everyday lives. The DEXA scan involves exposure to a similar amount of radiation as a flight from Auckland to Wellington. The pqCT muscle scan involves a slightly higher dose of radiation similar to an international flight.

There are minor risks involved in muscle biopsy, including bleeding, bruising, muscle soreness or infection. Our research staff will explain all of this to you in detail, and you will be welcome to ask questions. You may feel some discomfort from the biopsies on the day after the study. Again, staff will be available to answer any questions and advise you about any problems that you may experience.

The supplements you will be given contain fats which form a regular part of the diet. You dose you will be given is around 5 times more than you would usually eat from the diet. Previous studies have found that no adverse effects of this in young healthy males. If you have any pre-existing condition you will not be able to participate because it is not known whether it could be made worse by the supplement.

Benefits of participating include: (1) You will receive the allocated supplement free of charge for 1 month, (2) you will learn more about how your body responds to exercise and whether such supplement may benefit to you. (3) You will contribute to scientific evidence of whether these supplements work and how.

Research personnel will monitor you during the trial for any side effects of the treatment. The research will be stopped should any harmful effects appear or if research investigators feel that it is not in your best interest to continue. Any symptoms that you may experience will be recorded as part of the trial. If any new information becomes available during the course of the research about the treatments it will be shared by your investigator with you.

Will there be genetic testing?

We will measure the amount of some of your genes, proteins and metabolites because they can change rapidly after exercise and may provide a biomarker of muscle function. There is no one gene, protein or metabolite that makes muscles strong or weak, but a number of small changes which contribute to muscle function. We will NOT be testing other genetic diseases that you could be carrying.

How will my samples be stored?

We will analyze your blood samples in Auckland for amino acids, gene and metabolite levels. We need to send some of your muscle samples to a specialist laboratory overseas to determine protein synthesis rates. Blood and muscle samples will be stored in secure freezers in an access restricted area at the University of Auckland, until analysis is completed. There will be no future unspecified research made on your samples without your prior approval. Any remaining human tissue following analysis
Compensation

In the event of an injury during the study you have a right to ACC compensation. In case of any adverse event which is found to be related to the administration of the treatment resulting in hospitalization, the charges for treatment will be covered by ACC.

Confidentiality

Research files and all other information that you provide will remain strictly confidential. No material that could personally identify you will be used in any reports on this research. Upon completion of the research your records will be stored for 2 years in a secure place under the responsibility of the investigators. All computer records will be password protected. Results from gene tests and other analysis performed in a research laboratory will not routinely be made available to you. However, a copy of your results will be given to you upon completion of the research at your request.

Finally

Thank you for considering your participation in this study

Ngā Tāngata hei whakapānga atu - For more information please contact:

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This research has received Ethical Approval from the Northern Health and Disability Ethics Committee

The principal investigators of the research are:

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Please keep this information sheet for your records.
Subject Name: ___________________________________ Date of Birth: ___/___/______

Effects arachidonic acid supplementation on skeletal muscle

CONSENT FORM

I have read and I understand the Patient Information Sheet dated ___________ and wish to take part in the research entitled “Effects arachidonic acid supplementation on skeletal muscle” which is designed to investigate the effects of arachidonic acid on protein metabolism and muscle remodelling.

I have had the opportunity to discuss this research with the investigator. I am satisfied with the answers I have been given.

1. I have had the opportunity to use support from a family (whanau) member or a friend to help me ask questions and understand the research. [ ]

2. I understand that taking part in this research is voluntary (my choice), and that I may withdraw from the research at any time and this will in no way affect my future or continuing health care. [ ]

3. I understand that my participation in this research is confidential and that no material which could identify me will be used in any reports on this research. I understand that the sponsor of the research, others working on the sponsor’s behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current research and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

4. I understand that the treatment, or investigation, will be stopped if it should appear harmful to myself. [ ]

5. I understand the compensation provisions for this research. [ ]

6. I have had time to consider whether to take part. [ ]

7. I know whom to contact if I have any side effects from the research. [ ]

8. I know whom to contact if I have any questions about the research. [ ]

9. I agree not to restrict the use of any data or results that arise from this research provided such a use is only for scientific purpose(s) [ ]

Participant to complete: Please circle as appropriate

| I consent to participate in the “Effects arachidonic acid supplementation on skeletal muscle” study | Yes | No |
| I wish to receive a copy of the results. I understand that there may be a specific delay between data collection and the publication of the research results | Yes | No |

Participant Signature: __________________________
Effects arachidonic acid supplementation on skeletal muscle

CONSENT FORM

Participant to complete:

I ______________________________ Print full name
of ______________________________ Print address

______________________________
______________________________
hereby consent to take part in this research which is designed to investigate the effects of immobilisation and exercise on muscle.

______________________________ Signature of Participant
______________________________ Date

Research Personnel to complete:

______________________________ Full name of Principal Investigator
______________________________ Signature of Principal Investigator
______________________________ Contact telephone number for PI

Research Personnel to complete:

______________________________ Project explained by
______________________________ Project role
______________________________ Signature
______________________________ Date

A copy of this consent form is to be given to the participant and to be kept in their research file.