

Physical, physiological and biochemical effects of AmLexin following exercise in healthy runners

Submission date 13/09/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/10/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/12/2021	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

AmLexin is a supplement with claims that it can keep joints healthy, protect joints from stress, support heart and joint health, keep bodies going strong and help people to bounce back from physical challenges. This study aims to show that AmLexin can support these claims through recruiting healthy people to take AmLexin whilst training for and completing a half-marathon, along with look at its effects on pain, stiffness, range of motion, mood and cellular oxidation.

Who can participate?

People aged 18-70 years old who are healthy and active and have the ability to train for and complete a half-marathon

What does the study involve?

Participants will be randomly allocated to one of two groups. One group will be given AmLexin to take twice daily for 8 weeks, whereas the other will be given a placebo to take twice daily for 8 weeks. During these 8 weeks, both groups will undergo training for a half-marathon. There will be a minimum of 3 training sessions per week (1 hour per session), with increasing difficulty. These sessions will focus on hill, interval and distance training. After completing the half-marathon, participants in both groups will be asked to take their supplement (AmLexin or placebo) for one more week.

What are the benefits and risks of participating?

Participants may or may not benefit from taking part in this study, depending on the effect of AmLexin on themselves. Participants may face a risk of temporary gastrointestinal discomfort associated with consuming an unfamiliar dietary supplement. Although each of the ingredients found in the supplement has been documented to be extremely safe, there is some possibility that participants, or an unborn child, may be subject to risks that have not been identified. There is a possibility of an allergic reaction to the nutritional supplement or placebo. Symptoms of allergy include rash, wheezing or difficulty breathing or swallowing, dizziness, swelling of the mouth, hands or eyes, a fast heart rate and sweating. Participants may experience muscle stiffness, pain and or injuries relating to the exercise program.

Where is the study run from?

1. Treehouse Athletic Club, Draper, UT (USA)
2. GLH Nutrition, LLC, Draper, UT (USA)

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

April 2017 to April 2018

Who is funding the study?

Unigen Inc. (USA)

Who is the main contact?

Lidia A Brownell

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Contact information

Type(s)

Scientific

Contact name

Ms Lidia Alfaro Brownell

Contact details

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98405

Additional identifiers

Protocol serial number

UNI1306-2

Study information

Scientific Title

Effects of AmLexin (Acacia Catechu and Morus Alba) on Redox and Subjective Pain in Healthy Physically Active Adults

Study objectives

To investigate the use of a dietary herbal supplement on healthy active subjects on measures of pain, stiffness, range of motion, psychological mood state and cellular oxidation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Aspireirb A WIRB Copernicus Group, 02/05/2017, Unigen2017

Primary study design

Interventional

Study design

Interventional randomised placebo-controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Pain, stiffness, range of motion, psychological mood state (wellbeing, mood, vigor) and cellular oxidation

Interventions

30 participants will be randomly allocated to the active group or the placebo group. This study is a double-blind study.

Participants in the active group will receive 400 mg AmLexin (Acacia catechu heartwood and Morus alba root) - 200 mg will be taken twice daily (once in the morning and once in the evening) for 8 weeks. Participants in the placebo group will be given a matched placebo containing white rice flour and starch, again to be taken once in the morning and once in the evening daily for 8 weeks.

During this 8 week period, participants will take part in a training program for a half-marathon run (13.1 miles). This will involve a minimum of 3 specific training runs of approximately 1 hour duration, with progressively higher intensity and duration each week. This includes at least one "hill" workout, one "interval" workout and one "distance" workout.

After completing the half-marathon run, participants in both groups will be asked to continue taking their allocated supplements for one week.

Intervention Type

Supplement

Primary outcome(s)

The following are assessed at the baseline, weekly during the training regimen (weeks 1, 2, 3, 4, 5, 6, 7 and 8), and daily for a week post half-marathon:

1. Range of motions (ROM), assessed using digital inclinometry
2. Pain, stiffness and activities of daily living, assessed using a visual analogue scale (VAS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Key secondary outcome(s)

1. Oxidation-reduction potential (ORP), assessed using the Luoxis' proprietary RedoxSYS Diagnostic System at the baseline and 7 days post-marathon
2. Profile of mood states, assessed using the Profile of Mood States Survey (POMS) at the baseline and 1 and 7 days post-marathon

Completion date

23/04/2018

Eligibility

Key inclusion criteria

1. Aged 18-70
2. BMI < 30 kg/m²
3. Healthy and active
4. No recurrent pain or limitations in range of motion
5. Ability to complete training for, and complete, a 13.1 mile half-marathon run
6. Willing to consume dietary supplements under investigation
7. Willing to undertake all protocol measurements and training regimens
8. Ability to understand and sign the informed consent form

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

All

Total final enrolment

30

Key exclusion criteria

1. Recurrent pain, use of pain medications or pain supplements
2. Pregnant or breastfeeding women
3. Inability to complete prescribed training regimen
4. Current use of other pain support supplement or over-the-counter drug

Date of first enrolment

22/07/2017

Date of final enrolment

18/08/2017

Locations**Countries of recruitment**

United States of America

Study participating centre

EQQIL/ GLH Nutrition
648 E. Rocky Knoll Lane
Draper
United States of America
84020

Study participating centre
Treehouse Athletic Club
1101 East Draper Parkway
Draper
United States of America
84020

Sponsor information

Organisation
Unigen Inc.

Funder(s)

Funder type
Not defined

Funder Name
Unigen Inc.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Lidia A Brownell (lbrownell@unigen.net)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/12/2018	07/12/2021	Yes	No