

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

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

lbrownell@unigen.net

## Contact information

### Type(s)

Scientific

### Contact name

Ms Lidia Alfaro Brownell

### Contact details

2121 South State Street

Tacoma

United States of America

98405

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Study design**

Interventional randomised placebo-controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**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 measure**

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)

**Secondary outcome measures**

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

**Overall study start date**

24/04/2017

**Completion date**

23/04/2018

## **Eligibility**

**Key inclusion criteria**

1. Aged 18-70
2. BMI < 30 kg/m<sup>2</sup>
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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

70 Years

**Sex**

Both

**Target number of participants**

30

**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.

**Sponsor details**

2121 south State Street

Suite 400

Tacoma

United States of America

98405

**Sponsor type**

Other

**Website**

www.unigent.net

## Funder(s)

**Funder type**

Not defined

**Funder Name**

Unigen Inc.

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal in 2018

**Intention to publish date**

04/11/2018

**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?
<a href="#">Results article</a>		31/12/2018	07/12/2021	Yes	No