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

Submission date	Recruitment status	[_] Prospectively registered
13/09/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/10/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/12/2021	Other	

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
2121 South State Street
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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/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

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?
Results article		31/12/2018	07/12/2021	Yes	No