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Impact of astaxanthin on health and performance among firefighters

Submission date 02/10/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/10/2023	**Overall study status** Completed	
Last Edited 02/12/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Astaxanthin is an antioxidant, which has been suggested to have a better antioxidant capacity. Studies with astaxanthin have shown reductions in inflammation and oxidative stress in addition to improvements in fat utilization for energy. Firefighters are exposed to various physical and psychological stressors that have been shown to increase their high risk of heart disease. Given the benefits of astaxanthin, firefighters might benefit from supplementation. The purpose of this study is to examine the effects of 4 weeks of 12 mg/day supplementation with AstaReal(R) Astaxanthin on markers of oxidative stress and inflammation in addition to the effects on substrate oxidation rates and firefighter task-specific performance.

Who can participate?
Healthy, career firefighters aged 18 - 60 years old.

What does the study involve?
Supplementation with either 12 mg/day natural astaxanthin from algae or placebo softgels for 4 weeks, followed by 2-week washout and another course of 4 weeks with either astaxanthin or placebo.

What are the possible benefits and risks of participating?
Possible benefits include improved antioxidant capacity, improved physical performance and endurance, reduced physical fatigue, improved cardiovascular health.

There are no known side effects of astaxanthin supplementation.

Where is the study run from?
Texas A&M University (USA)

When is the study starting and how long is it expected to run for? (what are the overall start and end dates?)
July 2021 to October 2022

Who is funding the study?
AstaReal Inc. (USA), a wholly owned subsidiary of Fuji Chemical Industries Co., Ltd. (Japan)

Who is the main contact?
Dr Karen Hecht, khecht@astarealusa.com

Contact information

Type(s)
Scientific

Contact name
Mr Drew Gonzales

Contact details
1112 TAMU
College Station
United States of America
77843
+1 979-458-1741
dg18@tamu.edu

Type(s)
Principal investigator

Contact name
Dr Richard Kreider

Contact details
1112 TAMU
College Station
United States of America
77843
+1 979-458-1741
rbkreider@tamu.edu

Type(s)
Public

Contact name
Dr Karen Hecht

Contact details
3 Terri Ln.
Unit #12
Burlington
United States of America
08016
+1 2067714407
khecht@astarealusa.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRB2020-1379F

Study information

Scientific Title
Impact of astaxanthin supplementation on markers of cardiometabolic health and tactical performance among firefighters

Study objectives
12 mg/d for four weeks of astaxanthin supplementation improves markers of oxidative stress, inflammation, cardiometabolic health, cardiorespiratory fitness, and occupational performance in career firefighters.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/07/2021, TAMU IRB (1112 TAMU, College Station, 77843, United States of America; +1 979.458.4067; irb@temu.edu), ref: IRB2020-1379F

Study design
Single-center interventional randomized double-blind placebo-controlled crossover trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Cardiovascular health and athletic performance

Interventions
Randomized Latin Square Design
Crossover study given 12mg astaxanthin for 4 weeks, 2 weeks washout then 4 weeks placebo OR placebo for 4 weeks, 2 weeks washout then 4 weeks 12mg astaxanthin.

Intervention Type
Supplement

Primary outcome(s)

1. Fasting blood advanced oxidation protein products, advanced glycated end products, and adiponectin were measured to assess oxidative stress via enzyme-linked immunosorbent assays following 28 days of supplementation with astaxanthin or placebo.
2. Fasting blood granulocyte-macrophage colony-stimulating factor [GM-CSF], interferon-gamma [IFN-γ], tumor necrosis factor-alpha [TNF-α], Interleukin[IL]-1β, IL-2, IL-4, IL-5, IL-6, IL-8, and IL-10 were measured to assess inflammation via Luminex multiplex assays pre- and post-exercise following 28 days of supplementation with astaxanthin or placebo.
3. Fasting blood lipids profiles (i.e., total cholesterol, high-density lipoprotein, low-density lipoprotein, non-high-density lipoprotein cholesterol, very-low-density lipoprotein cholesterol, low-density lipoprotein / high-density lipoprotein ratio, total cholesterol/ high-density lipoprotein ratio, and triglycerides) were measured to assess cardiometabolic health status pre- and post-exercise following 28 days of supplementation with astaxanthin or placebo.
4. Ventilatory anaerobic threshold, peak oxygen consumption, substrate oxidation rates, and time-to-exhaustion were measured to assess cardiorespiratory fitness by analyzing breath-by-breath volumes of oxygen consumption and carbon dioxide production on an incremental exercise stress test with a metabolic cart following 28 days of supplementation with astaxanthin or placebo.
5. Salivary cortisol, uric acid, and interleukin-1β were measured to assess the inflammatory and oxidative stress response to firefighter activities via enzyme-linked immunosorbent assays on post-supplementation salivary samples collected at pre- and post-firefighter-specific task assessment. The time points collected were 30 minutes and 5 minutes prior to the firefighter assessment, as well as 5 minutes and 3 minutes after the firefighter assessment following 28 days of supplementation with astaxanthin or placebo.
6. Time to complete, heart rate responses, and air utilization were measured to assess occupational performance before, during, and after the firefighter activities. Time to completion on the firefighter task assessment was noted as the total time it took to complete the battery of tasks; heart rate responses for the firefighter assessment were taken before, average during, and after the assessment; air utilization was assessed after the assessment by measuring pre- and post-assessment air tank pounds per square inch measurements following 28 days of supplementation with astaxanthin or placebo.

Key secondary outcome(s))

1. Fasting blood whole blood cell count (e.g., white blood cell count, red blood cell count, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, red blood cell distribution width, neutrophils, lymphocytes, monocytes, eosinophils, basophils, platelets), liver function markers (e.g., alkaline phosphatase, aspartate transaminase, alanine transaminase, total protein, albumin, globulin, albumin/globulin ratio, bilirubin), and renal function markers (e.g., glucose, sodium, potassium, chloride, carbon dioxide, calcium, blood urea nitrogen, creatinine, blood urea nitrogen /creatinine ratio, non-African American estimated glomerular filtration rate) were measured to assess clinical health and safety pre- and post-exercise following 28 days of supplementation with astaxanthin or placebo.
2. Body fat percentage was measured using a dual x-ray absorptiometry scan following 28 days of supplementation with astaxanthin or placebo.
3. Height and weight were measured using a Health-O-Meter Professional 500KL self-calibrating digital scale following 28 days of supplementation with astaxanthin or placebo. Furthermore, height and weight were used to calculate body mass index following 28 days of supplementation with astaxanthin or placebo.
4. Resting heart rate and blood pressure measurements were assessed via an automatic blood pressure monitor following 28 days of supplementation with astaxanthin or placebo.

5. Subjective stress was measured using the firefighter self-efficacy coping questionnaire following 28 days of supplementation with astaxanthin or placebo.
6. Perceived adverse effects were measured via the side effects questionnaire following 28 days of supplementation with astaxanthin or placebo.

Completion date
29/10/2022

Eligibility

Key inclusion criteria
1. They have a willingness to provide voluntary, written, informed consent to participate in the study;
2. They are healthy professional or volunteer male firefighters age 18 - 60 years;
3. They are free from any signs, symptoms, or diagnosis of any cardio-respiratory and/or metabolic disorders;
4. They are free from any known blood disorders (e.g., anemia, hemophilia);
5. They are free from any caffeinated supplements (e.g., thermogenics, pre-workouts, energy drinks, etc) consumption 24-hours prior to all testing sessions;
6. They are free from any alcohol and/or nicotine consumption 24-hours prior to all testing sessions;
7. They are free from ergogenic aids like creatine or testosterone boosters for at least two weeks prior to the initiation of the study;
8. They are resistance trained defined as participating in regular resistance training exercises for at least twice per week for the last six months;
9. They have no current or previous musculoskeletal injuries within the last year;
10. They are engaged in at least 150-minutes of moderate - intensity exercise per week for the last six months;
11. They do not have any known allergies to sunflower oil.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
Male

Total final enrolment
20

Key exclusion criteria
1. They use prescription or over-the-counter (OTC) products known to interact with astaxanthin within 72 hours of randomization and during the trial such as aspirin, clopidogrel and nonsteroidal anti-inflammatory drugs (NSAIDs);
2. They have any known allergies to sunflower oil or astaxanthin;
3. They are not resistance trained and defined by participating in regular resistance training exercises for at least twice per week for the last six months;
4. They are not engaged in 150-minutes of moderate - intensity exercise each week for the last six months;
5. They have any medical condition that would affect the ability to perform a standard exercise program;
6. They are a current smoker (cigarettes)

Date of first enrolment
01/01/2022

Date of final enrolment
15/08/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Texas A&M University
College Station
United States of America
77843

Sponsor information

Organisation
Texas A&M University

ROR
https://ror.org/01f5ytq51

Funder(s)

Funder type
Industry

Funder Name
AstaReal Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/11/2024	02/12/2024	Yes	No
Abstract results	p. 9	27/07/2023	03/10/2023	No	No