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Effects of calcium fructoborate on markers of subclinical atherosclerosis

Submission date
08/05/2012

Recruitment status
No longer recruiting

Registration date
24/05/2012

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Previous clinical studies have shown the anti-inflammatory and antioxidant characteristics of calcium fructoborate and suggest that this compound supports cardiovascular (heart) health. In particular, calcium fructoborate has been shown to lower CRP in patients with symptoms of osteoarthritis and stable angina pectoris. Further research suggests calcium fructoborate may lower blood levels of LDL-cholesterol and raise blood levels of HDL-cholesterol. The aim of our study is to assess the effects of FruiteX-B® Calcium Fructoborate on markers of subclinical atherosclerosis in a healthy population.

Who can participate?
This trial will include healthy men and women, age 40-60.

What does the study involve?
The study will take 30 days and participants will be randomly divided into two groups: one group will receive FruiteX-B® Calcium Fructoborate and the other group will be given a placebo (dummy drug). At the end of the study, we will compare the results of the blood clinical laboratory tests between the groups of participants.

What are the possible benefits and risks of participating?
The immediate benefit may be the reduction of inflammation and lipid markers. In the long term, the participants quality of life may be improved. There are no known risks of the study.

Where is the study run from?
Natural Research, Ltd. and the University of Medicine and Pharmacy, Craiova, Romania.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start mid 2012 and the trial will last for about 6 months.

Who is funding the study?
Natural Research, Ltd. and the University of Medicine and Pharmacy, Craiova, Romania.

Who is the main contact?
Prof Romulus Scorei
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Study website
http://www.naturalresearch.ro

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Research Project no.14/2012

Study information

Scientific Title
Effects of calcium fructoborate alone on markers of subclinical atherosclerosis in a healthy population

Study objectives
The purpose of this study is to assess the effects of FruiteX-B® Calcium Fructoborate alone on markers of subclinical atherosclerosis in a healthy population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee of the University of Medicine and Pharmacy from Craiova, Romania, 03/05/2012, ref: 431

Study design
Randomised double-blind placebo-controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Subclinical atherosclerosis in a healthy population

Interventions
Clinical study of FruitexB-X® mg versus placebo.
Study duration: 30 days, two doses per day.
Four time points: day 1, 4, 7, and 30
Placebo-controlled, double-blind study
Placebo material: 103 mg of fructose (the amount of fructose equivalent to what would be present in a 112 mg serving of FruiteX-B)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Blood clinical laboratory tests:
1. Fasting plasma glucose
2. Total, LDL and HDL cholesterol, triglycerides
3. High-sensitivity C-reactive protein (hs-CRP)
4. Metallic metalloproteinase-9 (MMP-9)
5. Monocyte chemotactic protein 1 (MCP-1)
6. Lipoprotein-associated phospholipase A(2) (Lp-PLA(2))
7. IL-6
8. Homocysteine
9. oxLDL

10. Vitamin D3 (Calcidiol)
11. Adiponectin
12. Insulin
13. PON-1
14. Isoprostanes

Secondary outcome measures
1. Clinical exam
2. 12-lead ECG
3. Ankle-brachial index

Overall study start date
30/06/2012

Completion date
30/12/2012

Eligibility

Key inclusion criteria
1. Male or female patients aged 40-60
2. Gender ratio: 50% females and 50% males
3. BMI range: 24-27 (overweight but not obese)
4. Normal or minor hypertension (<140/80-90)
5. Increased level of blood CRP (>3 mg/l)
6. Increased LDL (>130)
7. Increased triglyceride level (>200)
8. Reduced HDL level (<40)
9. Fasted glucose level (<100)
10. Informed consent obtained at selection

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150 healthy subjects; 100 on active therapy (FruiteX-B® at two separate daily serving sizes: 56 mg (28 mg twice daily) and 112 mg (56 mg twice daily), 50 on placebo

Key exclusion criteria
Subjects with nonphysiological and pathological conditions such as:
1. Cardiovascular (CV) symptoms (e.g., angina, shortness of breath, etc)
2. CV disease
3. Diabetes mellitus or renal failure
4. Infectious or inflammatory disease

5. Active allergy
6. Smokers
7. Subjects who consume more than two alcoholic beverages per day
8. Subjects using any supplements 30 days prior to the initiation of the study
9. Subjects using statins, anti-hypertensive, anti-hyperlipidemia, anti-inflammatory, or anti-diabetic medications

Date of first enrolment
30/06/2012

Date of final enrolment
30/12/2012

Locations

Countries of recruitment
Romania

Study participating centre
Natural Research Ltd
Craiova
Romania
200386

Sponsor information

Organisation
Natural Research Ltd (Romania)

Sponsor details
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Sponsor type
Industry

Website
http://www.naturalresearch.ro

Funder(s)

Funder type
Industry

Funder Name
Natural Research Ltd (Romania), ref: 14/2012

Funder Name
University of Medicine and Pharmacy, Craiova (Romania)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015	18/01/2019	Yes	No