

Calcium fructoborate effect on systemic inflammation and dyslipidaemia markers in middle-aged people with primary osteoarthritis

Submission date 23/02/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 17/03/2010	Overall study status Completed	☐ Protocol
Last Edited 29/12/2020	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Research Project no.12/2008

Study information

Scientific Title

A double-blind, placebo-controlled pilot study to evaluate FruitexB® (calcium fructoborate) effect on systemic inflammation and dyslipidaemia markers in middle-aged people with primary osteoarthritis

Acronym

FruiteB

Study objectives

The safe and efficacious use of the FruitexB® (chemical natural-identical plant based dietary boron) in other inflammatory diseases prompted us to do this study of its anti-inflammatory effects in patients with osteoarthritis (OA) symptoms. The main objective of this approach was to evaluate whether or not FruitexB®, in a double-blind, placebo-controlled, randomly allocated trial with patients suffering from knee osteoarthritis symptoms, may cause any statistically significant favourable effect on systemic inflammation and dyslipidemia markers when compared with the placebo group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Ethics Committee of the University of Medicine and Pharmacy of Craiova, Romania, approved in March 2008 (ref: 364/2008). The trial is also in compliance with the Helsinki Declaration of 1975 as revised in 1983.

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled single centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Primary osteoarthritis

Interventions

The study was double-blind and placebo-controlled. For ease of presentation the four subject groups are given the following descriptors:

Group 1: 30 mg FruitexB® twice per day

Group 2: 60 mg FruitexB® twice per day

Group 3: 120 mg FruitexB® twice per day

Group 4: 120 mg placebo twice per day. Placebo material was based on fructose only.

The duration of the treatment was 2 weeks, administered as 2 capsules twice per day (BID) ingested orally with meals. Survey on dietary intake was carried out by personal interview. Interviewers presented tableware and food models and investigated the meal intake on 2 different weekdays and 1 weekend day based on recall method. Nutrient intake was calculated by use of the DietSYS+Plus (version 5.9), dietary analysis program (Block Dietary Data Systems). The DietSYS+Plus database, a software that analyses nutrients, was expanded for the present

study to include dietary boron values in foods consumed in Romania. After calculating the intake of nutrients per individual, percentage of the intake was calculated in relation to Dietary Reference Intakes for Romania. Subsequently, boron intake was calculated using the boron content database of the foods commonly consumed by Romanian urban and rural people. We utilised the analytical B nutrient database that was previously developed for the purpose of estimating B intake.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

FruitexB® (calcium fructoborate)

Primary outcome(s)

Determination of biochemical parameters. Blood samples for biochemical analyses were taken from fasting venous blood in the morning at the start, and after 2 weeks of treatment. Commercial tubes without anticoagulant were used to collect blood for determination of biochemical parameters. Basic biochemical parameters, lipid profile (total cholesterol, high density lipoprotein [HDL-], low density lipoprotein [LDL-] cholesterol, and inflammatory markers (C-reactive protein [CRP], erythrocyte sedimentation rate [ERS] and fibrinogen) were analysed in serum by standard biochemical procedures using the Hitachi 911 automatic analyser and kits (Roche, Switzerland). Due to known correlations between selected markers, the following ratios were used for processing the data: CHOL/CRP and HDL/CRP.

Key secondary outcome(s)

In neurological literature on diabetic peripheral neuropathy, several neuropathic symptoms and signs scales have been developed, such as the Neurological Symptom Score, the extensive Neuropathy Symptom Profile, and the Neurological Disability Score [B]. These physician-based scales are used primarily in diabetic neuropathy trials in order to diagnose the absence or presence of peripheral neuropathy, although the Neurological Symptom Score does not emphasise actual severity of complaints. Furthermore, consensus guidelines have been published on quantitative sensory testing [B], and on standardised measures in diabetic neuropathy [B]. We used said guidelines to determine paresthesias numbness.

These were measured at the first visit in the day when study begun, and the next measure was done after 2 weeks.

Completion date

30/08/2009

Eligibility

Key inclusion criteria

1. Men and non-pregnant women
2. Aged 40 - 85 years
3. Primary OA of at least one knee as demonstrated by a radiological examination carried out

within the previous 3 months

4. Body mass index (BMI) less than 28 and greater than 24.4 kg/m²

5. Elevated blood levels of at least one inflammatory marker

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

72

Key exclusion criteria

1. Individuals with digestion problems
2. Subjects with a fever and/or under treatment with antibiotics
3. Subjects with fructose intolerance
4. Subjects taking any painkillers and/or vitamin B6
5. Subjects taking aspirin
6. Current use of non-steroidal anti-inflammatory drugs (NSAIDS) and acetaminophen

Date of first enrolment

10/03/2008

Date of final enrolment

30/08/2009

Locations

Countries of recruitment

Romania

Study participating centre

a.i.cuza no.13

Craiova

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Sponsor information

Organisation

Natural Research, Ltd (Romania)

Funder(s)**Funder type**

Industry

Funder Name

Natural Research, Ltd (Romania) - Research Project (ref: 12/2008)

Funder Name

University of Medicine and Pharmacy of Craiova (Romania)

Results and Publications**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	01/12/2011	29/12/2020	Yes	No