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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

Registration date
17/03/2010

Overall study status
Completed

Last Edited
29/12/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

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
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 useing 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 measure
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.

Secondary outcome measures
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.

Overall study start date
10/03/2008

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/m^2
5. Elevated blood levels of at least one inflammatory marker

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 patients

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 acetominophen

Date of first enrolment
10/03/2008

Date of final enrolment
30/08/2009

Locations

Countries of recruitment
Romania

Study participating centre
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Sponsor information

Organisation
Natural Research, Ltd (Romania)

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Sponsor type
Industry

Website
http://www.naturalresearch.ro/

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

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	01/12/2011	29/12/2020	Yes	No