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Effects of resveratrol combined with calcium fructoborate (Fruitex B) in patients with stable angina pectoris

Submission date 21/03/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/03/2010	**Overall study status** Completed	
Last Edited 25/03/2010	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Romulus Scorei

Contact details
a.i.cuza no.19
Craiova
Romania
200385
+40 (0)251 41 59 60
romulus_ion@yahoo.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Research Project no.13/2010

Study information

Scientific Title
Effects of resveratrol combined with calcium fructoborate (Fruitex B) in patients with stable angina pectoris. A 60 days double-blind-controlled pilot study

Acronym
Res-FruitexB

Study objectives
The purpose of this study is to assess the short-term effects of Resveratrol combined with Calcium Fructoborate on the clinical and inflammatory status of patients presenting with stable angina pectoris.
Resveratrol, a polyphenol phytoalexin, possesses diverse biochemical and physiological actions, including estrogenic, antiplatelet, and anti-inflammatory properties. Resveratrol has been shown to improve health and slow the progression of disease in various models. Several cardioprotective mechanisms have been identified including antioxidant, anti-inflammatory, and anti-fibrotic actions. Each of these actions is thought to have the ability to attenuate the pathophysiology underlying the cardiac structural remodelling which results from acute myocardial infarction. Both in acute and in chronic models, resveratrol attenuates myocardial ischemic reperfusion injury, atherosclerosis, and reduces ventricular arrhythmias.
Boron compounds are known to show a variety of different biological activities. The soluble carbohydrate compounds of B buffer the reactive species of oxygen by developing organic peroxyborates. Boron exhibits inhibitory action on various enzymes, and particularly on prostaglandin endoperoxide synthases COX-1 and COX-2.

It is more ethically justified to use active components in each group. Therefore this is a comparative study rather than placebo-controlled study. Besides, it may show synergy between FrxB and Resveratrol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee of the Cardiology Center of University of Medicine and Pharmacy of Craiova, Romania, approved in February 2010 (ref: 400/2010)
The trial is also in compliance with the Helsinki Declaration of 1975 as revised in 1983

Study design
Randomised double blind active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Stable angina pectoris

Interventions
The study was double-blind and controlled. Patients will be randomised to the following groups
1. Combination of FrxB (120mg) with Resveratrol (10mg)
2. FrxB only
3. Resveratrol only
Study drugs will be taken orally and daily over 60 days. There will be no follow up beyond the end of the intervention.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Ischemic cardiovascular events
2. The quality of life (Seattle Angina Questionnaire)
3. Serum High-Sensitivity C-Reactive Protein (hsCRP)
All outcomes will be assessed at baseline and at the end of the study period (2 months)

Secondary outcome measures
1. Cardiac arrhythmias, assessed by standard transthoracic echocardiography (ECG)
2. Other cardiovascular markers
2.1. Sodium
2.2. Potassium
2.3. Creatinine
2.4. Alanine aminotransferase (ALT)
2.5. Aspartate aminotransferase (AST)
2.6. Fasting plasma glucose
2.7. Total cholesterol
2.8. Low Density Lipoprotein (LDL)-cholesterol
2.9. High Density Lipoprotein (HDL)-cholesterol
2.10. N-terminal prohormone brain natriuretic peptide (NT-proBNP)
All outcomes will be assessed at baseline and at the end of the study period (2 months)

Overall study start date
30/03/2010

Completion date
30/09/2010

Eligibility

Key inclusion criteria
1. Male or female patients ≥ 18 years
2. Diagnosis of angina pectoris (Class II-IV, Canadian Cardiology Society)
3. Informed consent obtained at selection

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 patients

Key exclusion criteria
1. Unlikely to cooperate in the study
2. Legal incapacity or limited legal incapacity
3. Women who are pregnant, breast-feeding or women of childbearing potential
4. Participation in another drug or device trial at the same time or within the previous 30 days (or within 5 drug half-lives of the investigational drug, or within the time legally required by regulatory authorities, whichever are longer)
5. Known alcohol or drug abuse, known moderate or severe liver disease (Child-Pugh score > 7) or known severe renal disease (serum creatinine > 220 micromoles/L) or known anaemia (blood haemoglobin < 11 g/L)

Date of first enrolment
30/03/2010

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
Romania

Study participating centre

a.i.cuza no.19
Craiova
Romania
200385

Sponsor information

Organisation
Natural Research, Ltd (Romania)

Sponsor details
ai cuza no.19
Craiova
Romania
200385
+40 (0)251 41 59 60
romulus_ion@yahoo.com

Sponsor type
Industry

Website
http://www.naturalresearch.ro

Funder(s)

Funder type
Industry

Funder Name
Natural Research, Ltd (Romania) - Research Project (ref: 13/2010)

Funder Name
Cardiology Centre of 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