

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

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>21/03/2010   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>25/03/2010 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>25/03/2010       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

**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.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

## **Study type(s)**

Treatment

## **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(s)**

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)

**Key secondary outcome(s)**

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)

**Completion date**

30/09/2010

**Eligibility****Key inclusion criteria**

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

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

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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: 13/2010)

**Funder Name**

Cardiology Centre of 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