

# Selenium/zinc administration in human malabsorption cardiomyopathy

<b>Submission date</b> 15/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/11/2010	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <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

## Study information

**Scientific Title**  
Randomised clinical trial on selenium/zinc administration in human malabsorption cardiomyopathy

**Study objectives**  
Intestinal malabsorption is associated with trace elements deficiency and cardiomyopathy. The study will test the efficacy of selenium/zinc intravenous (i.v.) administration in reverting the malabsorption associated cardiac dilation and dysfunction.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics Committee of "La Sapienza" University of Rome approved on the 30th November 1997

## **Study design**

Single centre randomised controlled clinical study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Malabsorption related dilated cardiomyopathy

## **Interventions**

1. Intervention group: selenium and zinc i.v. administration (Addamel N 10 ml corresponding to Se 300 µg and Zn 13.6 mg)
2. Control group: no treatment

Patients will be randomly assigned to receive standard anti-heart failure therapy alone or associated with i.v. selenium and zinc administration every day for 1 week and every week for 6 months.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Selenium, Zinc

## **Primary outcome(s)**

1. Improvement in heart failure symptoms as evaluated by New York Heart Association (NYHA) class
2. Improvement in cardiac dimension and function by echocardiography (ejection fraction, end diastolic diameter, end diastolic volume, diastolic function assessment)
3. Normalisation of the selenium/zinc levels at neutron activation analysis

Primary and secondary outcome measures will be performed at baseline and after 6 months, i.e. at the end, of treatment.

## **Key secondary outcome(s)**

1. Recovery of cardiomyocyte degeneration as evaluated at histology
2. Increase of glutathione peroxidase activity in myocardial tissue

Primary and secondary outcome measures will be performed at baseline and after 6 months, i.e. at the end, of treatment.

**Completion date**

31/12/2010

## Eligibility

**Key inclusion criteria**

1. Male and female patients aged 18 - 70 years with intestinal malabsorption due to intestinal bypass because of severe obesity
2. Dilated cardiomyopathy lasting more than 6 months unresponsive to conventional supportive therapy (ejection fraction [EF] less than 40%)
3. Patients consent to endomyocardial biopsy study before and after six months treatment
4. Serum and myocardial deficiency of selenium/zinc demonstrated by neutron activation analysis

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patients with specific heart muscle diseases at histology (i.e. myocarditis)
2. Normal levels of myocardial trace elements

**Date of first enrolment**

01/01/1998

**Date of final enrolment**

31/12/2010

## Locations

**Countries of recruitment**

Italy

**Study participating centre**

**Viale del Policlinico 155**

Rome

Italy

00161

## **Sponsor information**

### **Organisation**

La Sapienza University (Italy)

### **ROR**

<https://ror.org/02be6w209>

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

La Sapienza University (Italy)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration