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# Selenium/zinc administration in human malabsorption cardiomyopathy

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 15/10/2010 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 02/11/2010 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 02/11/2010 | Circulatory System | [ ] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

## 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

## 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
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 measure
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.

### Secondary outcome measures
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.

### Overall study start date
01/01/1998

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
18

### 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
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## Sponsor information

### Organisation
La Sapienza University (Italy)

### Sponsor details
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### Sponsor type
University/education

### Website
http://www.uniroma1.it

### ROR
https://ror.org/02be6w209

# Funder(s)

**Funder type**
University/education

**Funder Name**
La Sapienza University (Italy)

# 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