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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

Protocol serial number
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

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