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

Contact name

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Contact details

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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

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 Italy 00161

Sponsor information

Organisation

La Sapienza University (Italy)

Sponsor details

Viale del Policlinico 155 Rome Italy 00161 +39 064 99 70 785 biocard@inmi.it

Sponsor type

University/education

Website

http://www.uniroma1.it

ROR

https://ror.org/02be6w209

Funder(s)

Funder typeUniversity/education

Funder Name La Sapienza University (Italy)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration