Effect of omacor on heart rate variability (HRV) parameters in patients with recent uncomplicated myocardial infarction

Submission date	Recruitment status	[X] Prospectively registered	
13/10/2003	No longer recruiting	[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
13/10/2003	Completed Condition category	Results	
Last Edited		Individual participant data	
08/08/2008	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 S1853001

Study information

Scientific Title

Study objectives

To evaluate the effect of Omacor on time-domain heart rate variability (HRV) parameters in comparison to placebo in patients with recent uncomplicated transmural myocardial infarction.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

A randomised, parallel group, double-blind, placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Myocardial infarction

Interventions

Based on the inclusion criteria, a first 24-hour Holter recording will be performed. Two to five days later, screened patients still eligible for the study will undergo a second 24-hour Holter recording. After the second Holter recording, all patients will be randomly allocated to treatment with Omacor 1 g once daily (o.d.) or placebo o.d.

Patients will be followed-up in double-blind fashion for a six-month period after randomisation. Visits, including 24-hour Holter recording and assessment of adverse events, will take place at one-month intervals ± five days after randomisation, i.e., six times in all.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Omacor

Primary outcome measure

Superiority of Omacor to improve HRV from baseline to endpoint.

Secondary outcome measures

- 1. Improvement in time domain HRV indices
- 2. Safety

Overall study start date

01/01/2004

Completion date

01/01/2005

Eligibility

Key inclusion criteria

- 1. Males and females aged 40 years or older
- 2. Recent sustained acute myocardial infarction (AMI)
- 3. Women of childbearing age are subject to pregnancy testing and must agree to maintain adequate hormonal contraception
- 4. Signed informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100

Key exclusion criteria

- 1. Clinically or hemodynamically unstable condition
- 2. Further invasive investigation, a percutaneous transluminal coronary angioplasty (PTCA) or a coronary atrery bypass graft (CABG) are required
- 3. Sustained antiarrhythmic therapy (other than a beta-blocking agent administered in the context of secondary prevention of MI)
- 4. Severe concomitant illness (related to any body organ or system) that is likely to affect outcome assessment
- 5. Compliance problems
- 6. Participating in another trial within the past 30 days
- 7. Pregnant or lactating
- 8. Known hypersensitivity to the ingredients in Omacor or intolerability to olive oil
- 9. Diabetes mellitus type I and II

Date of first enrolment

01/01/2004

Date of final enrolment

01/01/2005

Locations

Countries of recruitment

Germany

Lithuania

Poland

Study participating centre

An der Trift 18

Hannover Germany 30559

Sponsor information

Organisation

Solvay Pharmaceuticals GmbH (Germany)

Sponsor details

Hans-Boeckler Alee 20 Hannover Germany 30173

Sponsor type

Industry

ROR

https://ror.org/01xscrc43

Funder(s)

Funder type

Industry

Funder Name

Solvay Pharmaceuticals GmbH (Germany)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Protocol	15/10/2003		Yes	No