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

Submission date 13/10/2003	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 13/10/2003	**Overall study status** Completed	
Last Edited 08/08/2008	**Condition category** Circulatory System	

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
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