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A randomised, controlled, factorial pilot study investigating omacor and/or fluvastatin in patients with chronic hepatitis C who have not responded to standard combination anti-viral therapy

Submission date
13/11/2007

Recruitment status
No longer recruiting

Registration date
27/03/2008

Overall study status
Completed

Last Edited
22/02/2019

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Maggie Bassendine

Contact details
Freeman Hospital
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Additional identifiers

EudraCT/CTIS number
2006-004335-29

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MRC ref: G0502028; EudraCT: 2006-004335-29

Study information

Scientific Title
A randomised, controlled, factorial pilot study investigating omacor and/or fluvastatin in patients with chronic hepatitis C who have not responded to standard combination anti-viral therapy

Acronym
HCV Lipid Study

Study objectives
Null hypotheses:
1. Omacor (low dose or high dose) treatment will have no effect on hepatitis C viral load
2. Fluvastatin treatment will have no effect on viral load

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Fife and Forth Valley Research Ethics Committee, 09/05/2007, ref: 07/S0501/21

Study design
Randomised open 3 x 2 factorial 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
Chronic hepatitis C infection

Interventions
Patients will be randomised to either:
Group 1: olive oil capsules daily for 12 weeks
Group 2: omacor 1 g daily for 12 weeks

Group 3: omacor 2 g daily for four weeks increasing to 1 g four times a day (q.d.s.) from weeks 5 - 12
Group 4: fluvastatin 40 mg daily for four weeks, then 80 mg daily from weeks 5 - 12, and olive oil capsules daily for 12 weeks
Group 5: omacor 1 g daily for 12 weeks, combined with fluvastatin 40 mg daily for four weeks, then 80 mg daily from weeks 5 - 12
Group 6: omacor 2 g daily for four weeks combined with fluvastatin 40 mg daily for four weeks, then omacor 1 g q.d.s and fluvastatin 80 mg daily from weeks 5 - 12

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Omacor, fluvastatin

Primary outcome measure
1. Fall in ALT from pre-treatment (average of screening and baseline visits) to end of treatment (EOT)
2. Fall in HCV viral load (lipoviroparticle [LVP] = putative infectious virion and/or total HCV RNA) from pre-treatment (average of screening and baseline visits) to EOT

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/12/2007

Completion date
30/04/2010

Eligibility

Key inclusion criteria
1. Age greater than or equal to 18 years
2. Positive hepatitis C ribonucleic acid (RNA) for more than six months
3. Elevated serum alanine transaminase (ALT) above normal limits for each laboratory
4. Previous lack of sustained virological response (SVR) to treatment with standard combination anti-viral therapy (standard interferon alpha and ribavirin and/or pegylated interferon alpha and ribavirin)
5. No lipid modulating agents for at least three months
6. Negative urine pregnancy test (for women of child bearing potential) documented within the 48 hour period prior to the first dose of test drug

Additionally all subjects must ensure adequate contraception during and for one month after treatment.

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72

Key exclusion criteria
1. Hepatitis B virus (HBV), hepatitis D virus (HDV) or human immunodeficiency virus (HIV) co-infection
2. A medical condition associated with chronic liver disease other than viral hepatitis, specifically excluding non-alcoholic fatty liver disease by body mass index (BMI) greater than or equal to 30
3. Clinical evidence of decompensated cirrhosis (ascites, portal hypertension with grade 2 oesophageal varices, hepatocellular cancer)
4. Alcohol use in excess of safe limits (28 units per week for men and 21 units per week for women)
5. Unable to conform to study protocol due to alcohol misuse or drug abuse
6. Serum alphafoetoprotein greater than or equal to 100
7. Platelet count less than 60,000 cells per/ml
8. Any research study within previous three months
9. Severe seizure disorder or concurrent phenytoin use
10. Lactation
11. History of muscular toxicity secondary to statins or fibrates
12. Hereditary muscle disorder or family history of hereditary muscle disorder
13. Concurrent anti-coagulant use

Date of first enrolment
01/12/2007

Date of final enrolment
30/04/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Freeman Hospital
Newcastle upon Tyne

United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Research and Development Department
4th Floor, Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK) (grant ref: AW-67446; G0502028)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	01/05/2014		Yes	No