

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

☐ Prospectively registered

☐ Protocol

Registration date

27/03/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

22/02/2019

Condition category

Infections and Infestations

☐ 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