ISRCTN24461054 https://doi.org/10.1186/ISRCTN24461054

Health benefits from anti-viral therapy for mild chronic hepatitis C

Submission date	Recruitment status	[_] Prospectively registered
25/04/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/11/2022	Infections and Infestations	

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

HTA 95/24/03

Study information

Scientific Title
Health benefits from anti-viral therapy for mild chronic hepatitis C

Study objectives
A multicentre, randomised study comparing interferon and ribavarin with no treatment for patients with mild chronic Hepatitis C.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 23/07/2007: Ethics committee approval was obtained both centrally (MREC/98/2/12) and from each Local Centre Committee (LREC).

Study design
Multicentre, randomised, controlled, non-blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Infection and infestations: Hepatitis

Interventions
Please note that, as of 14 January 2008, the anticipated end date of this trial has been updated from 31 July 2001 to 31 October 2003.

Interventions:
1. Interferon and ribavarin
2. No treatment

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Interferon and ribavarin

Primary outcome measure
Primary outcome measure updated as of 24/07/2007:
Sustained Virological Response (SVR) at 24 weeks post-treatment.

Primary outcome measure provided at time of registration:
Analysis includes health economics, quality of life and virological end points.

Secondary outcome measures
Secondary outcome measures added as of 24/07/2007:
1. Baseline factors predicting SVR
2. Changes in histopathology
3. Health-Related Quality of Life (HRQoL)
4. Viral kinetics: the relationship of early viral kinetics to final treatment outcome
5. Adverse events

Overall study start date
01/08/1998

Completion date
31/10/2003

Eligibility

Key inclusion criteria
Inclusion criteria updated as of 24/07/2007:
1. Adult, male or female, minimum age of 18 years
2. Serum positive for HCV by quantitative Polymerase Chain Reaction (qPCR) assay
3. Liver biopsy within 1 year before entry to the protocol. Histological diagnosis consistent with mild chronic hepatitis (Ishak necroinflammatory score <4, fibrosis score <3)
4. Compensated liver disease with the following minimum haematological, biochemical and serological criteria at the screening visit:
4.1. Haemoglobin (Hb) ≥12 g dl1 for women and ≥13 g dl1 for men
4.2. White Blood Cell count (WBC) ≥ 3000 mm3
4.3. Granulocyte count ≥1500 mm3
4.4. Platelets ≥100,000 mm3
4.5. Prothrombin time/ International Normalised Ratio (INR) within normal limits
4.6. Bilirubin within normal limits (unless non-hepatitis-related factors such as Gilberts disease explain a rise)
4.7. Albumin stable and within normal limits
4.8. Serum creatinine within normal limits
4.9. Fasting blood sugar within normal limits for non-diabetic patients
4.10. Glycosylated haemoglobin (HbA1c) <8.5% for diabetic patients (whether diet controlled or on medication)
4.11. TSH within normal limits (patients requiring medication to maintain Thyroid-Stimulating Hormone (TSH) levels in the normal range were eligible if all other inclusion/exclusion criteria were met)

4.12. AntiNuclear Antibodies (ANA) <1:160
4.13. Anti-HIV antibody negative
4.14. Serum hepatitis B surface antigen (HBsAg) negative
5. Confirmation and documentation that sexually active patients of childbearing potential were practising adequate contraception during the treatment period and for 6 months after discontinuation of therapy. A serum pregnancy test was obtained at entry before the initiation of treatment and had to be negative. Female patients could not breast-feed.

Inclusion criteria provided at time of registration:
Patients with hepatitis C

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
204

Key exclusion criteria
Exclusion criteria added as of 24/07/2007:
1. Prior treatment with interferon-alpha or ribavirin
2. Hypersensitivity to interferon-alpha or ribavirin
3. Participation in any other clinical trial within 30 days of entry to this protocol
4. Treatment with any investigational drug within 30 days of entry to this protocol
5. Prior treatment for hepatitis with any other antiviral or immunomodulatory drug within the previous 2 years
6. Any other cause for the liver disease other than chronic hepatitis C, including but not limited to:
6.1. Coinfection with hepatitis B virus
6.2. Haemochromatosis (iron deposition >2+ in liver parenchyma)
6.3. Alpha1-antitrypsin deficiency
6.4. Wilsons disease
6.5. Autoimmune hepatitis
6.6. Alcoholic liver disease
6.7. Obesity-induced liver disease
6.8. Drug-related liver disease
7. Haemophilia or any other condition preventing the patient from having a liver biopsy, including anticoagulant therapy
8. Haemoglobinopathies (e.g. thalassaemia)
9. Evidence of advanced liver disease, such as history or presence of ascites, bleeding varices, encephalopathy
10. Patients with organ transplants
11. Any known pre-existing medical condition that could interfere with the patients participation

in and completion of the
protocol such as:
11.1. Pre-existing psychiatric condition (e.g. severe depression, or a history of severe psychiatric disorder)
11.2. CNS trauma or seizure disorder requiring medication
11.3. Significant cardiovascular dysfunction within the past 6 months (e.g. angina, congestive cardiac failure, recent myocardial infarction, severe hypertension or significant arrhythmia)
11.4. Patients with an ECG showing clinically significant abnormalities
11.5. Poorly controlled diabetes mellitus
11.6. Chronic pulmonary disease (e.g. chronic obstructive pulmonary disease)
11.7. Immunologically mediated disease (e.g. inflammatory bowel disease, Crohns disease, ulcerative colitis, rheumatoid arthritis, idiopathic thrombocytopenic purpura, systemic lupus erythematosus, autoimmune haemolytic anaemia, scleroderma, severe psoriasis, cryoglobulinaemia with vasculitis)
11.8. Any medical condition requiring, or likely to require during the course of the study, chronic systemic administration of steroids
11.9. Gout
12. Substance abuse, such as excessive alcohol intake (>50 g day1) or erratic use of intravenous or inhaled drugs
13. Patients with clinically significant retinal abnormalities
14. Any other condition which in the opinion of the investigator would make the patient unsuitable for enrolment or that could interfere with the patient participating in or completing the protocol

Date of first enrolment
01/08/1998

Date of final enrolment
31/10/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

Organisation

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Sponsor type
Government

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ROR
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Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	HTA monograph	01/07/2006		Yes	No