Fluvoxamine for fatigue in primary biliary cirrhosis and primary sclerosing cholangitis: a randomised controlled trial.

Submission date	Recruitment status	Prospectively registered
11/07/2004	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/07/2004	Completed	[X] Results
Last Edited	Condition category	Individual participant data
10/08/2007	Digestive System	

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

N/A

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised 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

Primary biliary cirrhosis and primary sclerosing cholangitis

Interventions

Fluvoxamine treatment (150 mg/day) for a six-week period versus treatment with placebo. A double-blind placebo-controlled randomised trial.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Fluvoxamine

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2001

Completion date

01/06/2002

Eligibility

Key inclusion criteria

Patients with primary biliary cirrhosis or primary sclerosing cholangitis and chronic significant fatigue.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

33

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2001

Date of final enrolment

01/06/2002

Locations

Countries of recruitment

Netherlands

Study participating centre Albert Schweitzerplaats 25

Dordrecht Netherlands 3318AT

Sponsor information

Organisation

Foundation for Liver Research (Stichting Lever Onderzoek) (The Netherlands)

Sponsor details

Erasmus Medical Centre
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Sponsor type

Research organisation

ROR

https://ror.org/04hzejq44

Funder(s)

Funder type

Research organisation

Funder Name

Gastrostart foundation (The Netherlands) (ref: EUR 4537)

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 13/07/2004 Yes

No