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

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