

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
Registration date 12/07/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/08/2007	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pieter ter Borg

Contact details
Albert Schweitzerplaats 25
Dordrecht
Netherlands
3318AT
+31 (0)786541111
pterborg@zonnet.nl

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

ROR

<https://ror.org/04hzejq44>

Funder(s)

Funder type

Research organisation

Funder Name

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

Results and Publications

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