The effect of bezafibrate on itch in liver disease

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22138

Source
Nationaal Trial Register

Brief title
FITCH

Health condition

Primary biliary cirrhosis (PBC)
Primary sclerosing cholangitis (PSC)
Secondary sclerosing cholangitis (SSC)

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: Dutch Society of Gastroenterology (Nederlandse Vereniging voor Gastroenterologie (NVGE))

Intervention

Outcome measures

Primary outcome

Itch intensity score on a visual analogue scale (VAS)

Secondary outcome

-5D itch score: questionnaire for the evaluation of the 5 dimensions of itch and it’s impact on quality of life: duration, degree, direction, disability and distribution of itching;

-Serum ATX activity before, during and after treatment;

-Serum liver, kidney function and lipid profile parameters: AST, ALT, AP, γGT, albumin, creatinine, ureum, CK, VLDL-, LDL- and HDL-cholesterol and triglycerides before and after treatment;

-Number of adverse and serious adverse events during and within two weeks after treatment;

-The effect on fatigue and quality of life will be evaluated using the Liver Disease Symptom Index 2.0 questionnaire.

Study description

Study objective

Bezafibrate alleviates itch complaints in patients with cholestatic liver disease.

Study design

start of treatment (day 0); end of treatment (day 21); follow-up (day 35)

Intervention

bezafibrate 400mg once daily for 3 weeks

Contacts

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Eligibility criteria

Inclusion criteria

-Age ≥ 18 years;
-Understanding of Dutch, English, German, Spanish or Italian language;

-Diagnosed with primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC) or secondary sclerosing cholangitis (as defined by EASL clinical practice guidelines of cholestasis 2009 [19]).

-Itch without primary dermatologic abnormalities and with an intensity score of ≥ 5.0 cm on a scale from 0.0 cm (no itch) to 10.0 cm (worst itch possible), scored twice in the week before inclusion.

Exclusion criteria

-Concomitant guideline-recommended as well as experimental antipruritic therapy, e.g. rifampicin, opioid-receptor antagonists (naltrexon, naloxone), serotonin-reuptake inhibitors (sertraline), ondansetron, phenobarbital, propofol, lidocaine, dronabinol, butorphanol, internal or external biliary drainage, extracorporeal albumin dialysis, ultraviolet-B phototherapy;

NB. Topical menthol containing agents are allowed, as well as bile salt sequestrants (colesevelam, cholestyramin) as long as taken at least 4 hours before or after intake of the study medication. Incidental use of these agents should be noted by patients in the diary, structural use should be noted on the CRF (section co-medication);

-Pregnancy, women of childbearing potential not using contraception, breast feeding;

-Cholestasis due to obstruction that requires invasive desobstructive treatment within the time scope of the study (5 weeks), such as endoscopic retrograde cholangiopancreaticography (ERCP) or surgical removal of a tumour compressing the bile

duct;

-Use of opiates;

-Renal insufficiency (creatinine clearance <60mL/min per 1.73m2).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2015
Enrollment:	84
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-08-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42182
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5327
NTR-old	NTR5436
CCMO	NL48885.018.15
OMON	NL-OMON42182

Study results