The effect of bezafibrate on itch in liver disease

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Bezafibrate alleviates itch complaints in patients with cholestatic liver disease.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22138

Bron
Nationaal Trial Register

Verkorte titel
FITCH

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam
Overige ondersteuning: Dutch Society of Gastroenterology (Nederlandse Vereniging voor Gastroenterologie (NVGE))

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Itch intensity score on a visual analogue scale (VAS)

Toelichting onderzoek

Doel van het onderzoek

Bezafibrate alleviates itch complaints in patients with cholestatic liver disease.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

bezafibrate 400mg once daily for 3 weeks

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2015
Aantal proefpersonen:	84
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-08-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42182
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5327

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

Resultaten