COPE-trial: Colesevelam versus placebo in cholestatic pruritus, a double-blind placebo-controlled study

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Pruritus is a frequent and debilitating symptom in patients with Primary Biliary Cirrhosis, Primary Sclerosing Cholangitis and other cholestatic liver diseases. Aim is to assess the effect of Colesevelam on cholestatic pruritus.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON31774

Source
ToetsingOnline

Brief title
Colesevelam versus placebo in cholestatic pruritus

Condition

- Hepatic and hepatobiliary disorders

Synonym
cholestatic pruritus, itch in cholestatic liver disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Genzyme BV,Genzyme BV Naarden

Intervention

Keyword: cholestatic, colesevelam, pruritus

Outcome measures

Primary outcome

Primary endpoint:

40% reduction of pruritus according to visual analogue scores, comparison of

mean VAS score on T=18,19,20 to mean VAS score on T=-2, -1, 0.

Secondary outcome

Secondary endpoints:

Improvement in quality of life scores (T=0 compared to T=20)

Reduction in pruritus score/scratch lesions (T=0 compared to T=20)

Study description

Background summary

Pathofysiology of pruritus secundary to cholestasis remains largely unknown but it is generally believed that bile acids are etiologically involved. The principal pharmacological treatment options currently available are cholestyramine (a non-absorbable bile-acid binding resin), rifampicin and naltrexon. The efficacy of these drugs is limited and side-effects are common, in particular obstipation and nausea (cholestyramine), interaction with other treatments and toxic effects on the liver (rifampicin), and endogenous opioid-withdrawal syndrome (naltrexon). In addition, the efficacy of cholestyramine has never been investigated by placebo-controlled trials. This makes treatment of cholestatic pruritus frequently problematic and unsatisfactory. New treatment options are urgently needed.
Colesevelam (Cholestagel) seems a highly interesting new option. It is a bile acid sequestrant much more potent than cholestyramine but reportedly with an incidence of side-effects comparable to that of placebo. However, until now the efficacy of colesevelam in cholestatic pruritus has not been (adequately) tested.

Study objective

Pruritus is a frequent and debilitating symptom in patients with Primary Biliary Cirrhosis, Primary Sclerosing Cholangitis and other cholestatic liver diseases. Aim is to assess the effect of Colesevelam on cholestatic pruritus.

Study design

At least 38 patients with cholestatic pruritus will be included in an investigator-initiated, multicenter, double-blind, placebo-controlled trial. Patients will be treated with study medication (either colesevelam or placebo) for 3 weeks.

Intervention

Treatment with effective agent (colesevelam) or placebo

Study burden and risks

Adverse events of Colesevelam are comparable to those of placebo and cause limited burden.
Major risk for patients is to be withhold from anti-pruritic therapy for a maximum of 6 weeks.
3 weeks in case of a wash-out period for cholestyramine, another 3 weeks if randomized for placebo.
On the other hand, especially people who still have pruritus despite current therapy will tend to participate in this trial. For these patients participation might be beneficial.
Participation to this study is time-consuming, since a diary and questionnaires have to be filled out. This can be done at home or at out-patient clinic.
Participant won't be admitted to the hospital.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients with pruritus as a result of a cholestatic disorder
age above 18
informed consent

Exclusion criteria

Use of cholestyramine
Pregnancy
Inability to understand or speak Dutch language
Malignancy/Life expectancy<6 months

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-09-2008
Enrollment:	38
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cholestagel
Generic name:	Colesevelam
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	27-05-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-07-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-005981-11-NL
CCMO	NL20478.078.08