Somatostatin analogues as a volume reducing treatment of polycystic livers

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

Summary

ID

NL-OMON32446

Source
ToetsingOnline

Brief title
SOLVE

Condition

- Hepatic and hepatobiliary disorders

Synonym
polycystic liver disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ADPKD, lanreotide, octreotide, PCLD

Outcome measures

Primary outcome

Change in liver volume from baseline to 24 weeks.

Secondary outcome

Change in kidney volume from baseline to 24 weeks, change in symptoms from baseline to 24 weeks, change in quality of life from baseline to 24 weeks, proportion of patients that have any reduction of liver volume at 24 weeks, and adverse events during the 24 weeks.

Study description

Background summary

Polycystic liver disease is a disorder in which at least 20 liver cysts are present. It can occur in isolated autosomal dominant polycystic liver disease (PCLD) and in autosomal dominant polycystic kidney disease (ADPKD). De symptoms are due to the mass effect of the liver and include abdominal pain and distension, nauseau, vomiting, and early satiety. Until recent, no medical treatment was available for polycystic livers, but a few trials showed that the somatostatin analogues octreotide and lanreotide reduced liver volume in patients with a polycystic liver. However, there seems to be a difference in the effect on liver volume between octreotide and lanreotide. The liver volume of the patients who received octreotide 40 mg every 28 days during one year reduced with 4.9%, while the liver volume of the patients who received lanreotide 120 mg every 28 days during a half year reduced with 2.9%.

Study objective

With this trial we want to compare both somatostatin analogues, octreotide and lanreotide, in one trial, so we can see whether there is a difference in effect on liver volume in patients with polycystic livers. Furthermore, we want to find the optimal dosage of both octreotide and lanreotide.

Study design

This will be a randomized, open, parallel, clinical trial.

Intervention

The patients will be randomized to either the octreotide or the lanreotide group and will receive every 28 days for 24 weeks octreotide 60 mg or lanreotide 120 mg, respectively.

Study burden and risks

The treatment and CT scans go with certain risks, but in earlier trials with these drugs, the side effects were relatively mild and the patients had a subjectively reduction of their complaints. In conclusion, treatment with somatostatin analogues looks like an elegant alternative to surgical procedures that go with considerable morbidity.

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 polycystic liver disease
- at least 18 years of age
- Informed consent, patients are willing and able to comply with the study drug regimen and all other study requirements

Exclusion criteria

- kidney transplantation
- renal failure requiring hemodialysis
- use of oral contraceptives or estrogen suppletion
- women who are pregnant or breastfeeding

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-04-2011

Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Sandostatin LAR
Generic name:	octreotide
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Somatulin
Generic name:	lanreotide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	11-01-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-03-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2009-017849-57-NL
CCMO	NL30902.091.09