

THE EFFECTS OF RECOMBINANT HUMAN INSULIN-LIKE GROWTH FACTOR-1 ON THE NUTRITIONAL STATUS IN PATIENTS WITH LIVER CIRRHOSIS: A PILOT STUDY.

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The primary objective of this pilot study is to evaluate the effects of 6 months of recombinant human IGF-I (rhIGF-I) treatment on the body composition. The secondary objective is to assess the effects of the treatment on the liver function,...

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

Summary

ID

NL-OMON37474

Source

ToetsingOnline

Brief title

THE EFFECTS OF IGF-I IN LIVER CIRRHOSIS.

Condition

- Hepatic and hepatobiliary disorders

Synonym

liver cirrhosis

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Leveronderzoek

1 - THE EFFECTS OF RECOMBINANT HUMAN INSULIN-LIKE GROWTH FACTOR-1 ON THE NUTRITIONAL ...

15-06-2025

Source(s) of monetary or material Support: SLO - stichting lever onderzoek

Intervention

Keyword: INSULIN-LIKE GROWTH FACTOR-I, LIVER CIRRHOSIS, NUTRITIONAL STATUS

Outcome measures

Primary outcome

The study ends when all 6 patients have been treated with rhIGF-I for 6 months.

The nutritional status of the patients measured by body composition, liver function, respiratory quotient, resting energy metabolism and the quality of life.

Secondary outcome

The study will also end if serious adverse events occur.

Study description

Background summary

Insulin-like Growth Factor-I (IGF-I) is an anabolic hormone mainly produced in the liver. Patients with liver cirrhosis are characterized by IGF-I deficiency and malnutrition. There are studies that suggest that the suppletion of IGF-I in patients with liver cirrhosis can improve their nutritional status.

Study objective

The primary objective of this pilot study is to evaluate the effects of 6 months of recombinant human IGF-I (rhIGF-I) treatment on the body composition. The secondary objective is to assess the effects of the treatment on the liver function, respiratory quotient, resting energy metabolism and the quality of life.

Study design

Prospective open single-arm intervention study.

Intervention

The patients receive rhIGF-I 10 µg/kg twice daily as a subcutaneous injection for 6 months.

Study burden and risks

The burdens associated with participation: 6 blood samples; 12 outpatient clinic visits; 2 ward stay (1 stay of 2 days, 1 stay of 1 day); 7 history and physical examination; 2 dietary consults; 2 DXA-scans; 7 'quality of life' questionnaires; 2 indirect calorimetry; 2 handgrip strength and midarm muscle circumference test; 2 24 hours urinary nitrogen excretion. The benefit for the patients is an improved nutritional status which might lead to fewer complications due to cirrhosis. There is a risk of hypoglycemia for the patients that participate. However, careful preparations are taken to reduce the frequency and severity of this risk.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

18-70 years of age.;Liver cirrhosis.;Child Pugh score 6 or more.;Plasma IGF-I level below lower 2.5th percentile and adjusted for age (plasma IGF-I < -2 SD Z-score).;Willing and able to give informed consent.;Alcohol abstinence for at least 3 months before entering the study.;Eligible for liver transplantation, and being put on the liver transplant waiting list.

Exclusion criteria

Tense ascites requiring repeated paracenteses (two or more in the preceding year).;Severe peripheral edema.;Hospitalization for gastrointestinal bleeding, spontaneous bacterial peritonitis or other life-threatening complications within 3 months before entering the study.;Episode of encephalopathy requiring protein restriction, or hepatic encephalopathy that precludes participation.;Drug abuse.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2012

Enrollment: 6

Type: Anticipated

Medical products/devices used

Product type: Medicine

Brand name:	Increlex
Generic name:	mecasermine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO	
Date:	03-04-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	22-05-2012
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	EUCTR2012-001239-30-NL
CCMO	NL40114.078.12