# 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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| **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

**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

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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

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-05-2012 |
| Enrollment: | 6 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |

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

## Ethics review

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| 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 |