

# Progression of fibrosis in treated autoimmune hepatitis

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Identify markers predicting progression of fibrosis in treated autoimmune hepatitis patients

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Hepatic and hepatobiliary disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON52943

### Source

ToetsingOnline

### Brief title

Fibrosis in AIH

### Condition

- Hepatic and hepatobiliary disorders
- Autoimmune disorders

### Synonym

Autoimmune hepatitis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Maag Darm en Leverziekten

**Source(s) of monetary or material Support:** Ministerie van OC&W,Chiesi Farmaceutici,unrestricted grants from Zambon and Chiesi,Zambon

## Intervention

**Keyword:** Autoimmune hepatitis, Liver fibrosis

## Outcome measures

### Primary outcome

Main endpoint is a multivariate regression of treatment response, fibrosis and immunological markers for predicting increase in fibrosis as measured by liver elastography

### Secondary outcome

Amount of fibrosis at inclusion

Difference in fibrosis at inclusion and 5 years

Correlation between fibrosis markers, immunological markers and liver stiffness

Quality of life

## Study description

### Background summary

Autoimmune hepatitis, a chronic autoimmune disease of the liver is treated with immunosuppressants. One of the treatment goals in autoimmune hepatitis is the prevention of progression of fibrosis and development of cirrhosis. Although progression of fibrosis during therapy can occur knowledge of this phenomenon is limited.

### Study objective

Identify markers predicting progression of fibrosis in treated autoimmune hepatitis patients

### Study design

Multicenter, prospective observational cohort study

In all patients liver elastography and blood fibrosis markers and immunological markers will be determined yearly for a 5 year period. Patients will be asked

to fill out a questionnaire regarding quality of life.

### **Study burden and risks**

This is an observatory study and patients will not directly benefit. However, the study will increase the knowledge of fibrosis progression in autoimmune hepatitis from which patients may benefit in the long-term.

The burden the study adds is minor: Additional blood samples will be taken, liver elastography will be performed and patients will be asked to fill in a questionnaire.

## **Contacts**

### **Public**

Selecteer

Albinusdreef 2  
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### **Scientific**

Selecteer

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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 are older than 18 years old  
Patients with AIH (at least probable according to the simplified criteria) or overlapsyndrome  
Patients are treated for at least 6 months  
Patients have given written informed consent to participate in the study

## Exclusion criteria

Current flair of autoimmune hepatitis (ALT more than 3 times the upper limit of normal)  
Patients with signs of other liver diseases as NASH, alcoholic liver disease, viral hepatitis, hemochromatosis or Wilson's disease  
Patients with current decompensated liver disease (recompensated patients can be included)

## Study design

### Design

**Study type:** Observational invasive  
Masking: Open (masking not used)  
Control: Uncontrolled  
Primary purpose: Diagnostic

### Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 06-09-2019  
Enrollment: 300  
Type: Actual

## Ethics review

Approved WMO

Date: 22-07-2019  
Application type: First submission  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO  
Date: 06-08-2020  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO  
Date: 19-04-2022  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

## 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
CCMO	NL68801.058.19