# PROSPECTIVE STUDY OF THE PROGNOSTIC VALUE OF TRANSIENT ELASTOMETRY (FIBROSCAN) IN PRIMARY SCLEROSING CHOLANGITIS (PSC) PATIENTS (FICUS STUDY)

Published: 19-03-2015
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To determine the prognostic value of transient elastography (Fibroscan) in PSC patients.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Bile duct disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON41962

**Source**
ToetsingOnline

**Brief title**
FICUS study

### Condition

- Bile duct disorders
- Autoimmune disorders

**Synonym**
Primary sclerosing cholangitis. PSC. Bile duct disease.

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** MDL
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Fibroscan, FICUS, PSC

## Outcome measures

### Primary outcome

Transplant free survival

### Secondary outcome

* Prognostic value of Fibroscan on survival without liver transplantation (LT)

and without liver complications (ascites, variceal bleeding, hepatic

encephalopathy, hepatocellular carcinoma, cholangiocarcinoma, serum bilirubin

level above 6 mg/dL for at least 3 months, listing for LT).

* Time course of changes in liver stiffness

* Correlation of liver stiffness with:

o Histologic fibrosis (when liver biopsy available)

o Biologic markers of fibrosis : nonproprietary scores (APRI, FIB-4), other

markers*

* Comparison of fibroscan to established, and to be discovered, alternate

biomarkers of prognosis

# Study description

### Background summary

PSC is a rare (prevalence rate around 10/100.000 in northern European

descendants) and chronic cholestatic liver disease of unknown cause commonly associated with inflammatory bowel disease (IBD) and characterized by progressive obliterative fibrosis of the biliary tree. Although the natural course may be variable from one patient to another, PSC is often progressive, leading to biliary cirrhosis and its complications. In addition, one specific complication is the occurrence of cholangiocarcinoma whose early diagnosis is highly challenging. Overall, median survival ranges from 11 to 18 years. Several therapeutic modalities (medical, endoscopic and surgical) have been investigated. Unfortunately none except liver transplantation (LT) has been proven to alter the course of the disease significantly. Several prognostic models including clinical and biochemical parameters have been developed. However, it appears that these models are useful in predicting outcomes in patient cohorts but cannot reliably be used to predict outcome in an individual patient.

Advanced fibrosis is a major prognostic factor in all liver diseases, including PSC. Liver biopsy (LB) has traditionally been the standard for evaluation of fibrosis. However, LB is an invasive procedure that is prone to sampling errors and to intra- and interobserver variation. These limitations have fueled the development of noninvasive methods to assess liver fibrosis over the past decade. Fibrosis can be measured non invasively, based on a *biological* approach (quantifying biomarkers in serum samples) or based on a *physical* approach (measuring liver stiffness). In cholestatic diseases (primary biliary cirrhosis (PBC) and PSC), the diagnostic performance of current serum markers of fibrosis is lower than that of liver stiffness for detecting significant fibrosis.

Liver fibrosis can be staged using 1-dimensional ultrasound transient elastography (TE) which measures the velocity of a low-frequency (50 Hz) elastic shear wave propagating through the liver (Echosens, Paris, France). The stiffer the tissue, the faster the shear wave propagates. The results are expressed in kilopascals (kPa) and range from 2.5 to 75 kPa (normal value around 5 kPa). TE is a short time (< 10 minutes) and totally non-invasive procedure. TE has been implemented in many countries (more than 1300 devices worldwide) and no side effects have been ever reported. Numerous studies have shown a good correlation between liver stiffness and histologic stage of fibrosis in various chronic liver diseases, especially in chronic hepatitis C (CHC). The development of TE (and serum markers of fibrosis) has markedly reduced the need for liver biopsy analysis in CHC. Furthermore, it has been demonstrated that liver stiffness can predict 5-year survival of patients with CHC. Fibroscan is also used in other chronic liver diseases, including cholestatic diseases. In PBC or PSC, several studies have shown that TE has high accuracy in diagnosing significant fibrosis. Lastly, our group has recently demonstrated that liver stiffness is predictive of poor outcome (survival without liver complications) in PBC patients.

In most referral centers, Fibroscan is routinely performed in PSC patients.

Thus, there is a strong rationale for studying the prognostic value of liver stiffness in PSC, a severe liver disease without any prognostic models currently recommended in clinical practice. At the same time, search for accurate biomarkers of fibrosis and, more widely, of prognosis in PSC has to be done and compared to Fibroscan.

The International PSC Study Group (worldwide network of referral centers for PSC, www.ipscsg.org) provides a frame perfectly adapted to such a study.

### Study objective

To determine the prognostic value of transient elastography (Fibroscan) in PSC patients.

### Study design

International, prospective multicohort study

### Study burden and risks

Negligible burden or risk.

## Contacts

**Public**
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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

1. PSC diagnosis as defined by the European Association for the Study of the Liver (EASL) Practice Guidelines, including subgroups such as small duct PSC and auto-immune hepatitis *PSC overlap syndromes. There are no prohibited medications.
2. Age > 18 years and < 75 years
3. Written informed consent

### Exclusion criteria

1. Secondary sclerosing cholangitis (including IgG4-associated cholangitis)
2. Previous liver transplantation
3. Listed for liver transplantation
4. Presence of complication (ascites, encephalopathy, hepato-biliary malignancy)
5. Coexistent conditions that would limit life expectancy to less than 1 year
6. Associated liver disease of other etiology (chronic hepatitis B or C, chronic alcoholic liver disease, nonalcoholic steatohepatitis (NASH), hemochromatosis, Wilson*s disease or other significant liver disease)
7. Known pregnancy

## Study design

### Design

**Study type:** Observational invasive

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-06-2015 |
| Enrollment: | 50 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | Transient elastography (Fibroscan) |
| Registration: | Yes - CE intended use |

# Ethics review

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|---|---|
| Approved WMO Date: | 19-03-2015 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

# 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 | NL51339.018.14 |