SERVICE DE RADIOLOGIE ET D'IMAGERIE MEDICALE

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This study is registered at https://clinicaltrials.gov/ct2/show/NCT01789008?term=NCT01789008&rank=1
The registration identification number is NCT01789008.

Anita Kiani

Transient Elastography in the Determination of Advanced Fibrosis in Alcoholic Liver Disease. (FIBR-OH)

The recruitment status of this study is unknown because the information has not been verified recently.

Verified January 2013 by Rennes University Hospital.
Recruitment status was Recruiting

Sponsor:
Rennes University Hospital

Information provided by (Responsible Party):
Rennes University Hospital

ClinicalTrials.gov Identifier:
NCT01789008

First received: February 7, 2013
Last updated: February 8, 2013
Last verified: January 2013
History of Changes

Purpose

Alcoholic liver disease is the most frequent complication of excessive alcohol consumption. Early diagnosis of alcoholic liver disease is essential to avoid its complications that could be fatal. To date, the reference diagnostic tool is an invasive procedure: the liver biopsy. The transient elastography is a useful tool for early diagnosis of liver fibrosis. This tool is validated in the diagnosis of liver fibrosis due to C chronic hepatitis. Because it is non-invasive, fast, given immediate results; transient elastography could be repeated in alcoholic patients for liver fibrosis follow-up. In the present study, the investigators propose to realize liver biopsy and transient elastography in 300 alcoholic patients in weaning to evaluate the transient elastography accuracy in the exclusion of sever liver fibrosis (Metavir 3 and 4). The reference liver fibrosis diagnosis tool will be the liver biopsy.

Condition	Intervention
Alcoholism Liver Disease Liver Fibrosis	Other: liver biopsie

Study Type: Interventional
Study Design: Intervention Model: Single Group Assignment
Masking: Single Blind (Caregiver)
Primary Purpose: Diagnostic

Official Title: Interest of Transient Elastography in the Determination of Advanced Fibrosis in Alcoholic Liver Didease in Alcoholic Patients in Weaning.

Resource links provided by NLM:

MedlinePlus related topics: Liver Diseases

U.S. FDA Resources

Further study details as provided by Rennes University Hospital:

Primary Outcome Measures:

- Accuracy of transient elastography will be evaluated by AUC [Time Frame: 2 months] [Designated as safety issue: No]

Estimated Enrollment: 300
Study Start Date: February 2013
Estimated Primary Completion Date: February 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Transient elastography	Other: liver biopsie

A. Kharrat

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patients more than 18 years old; hospitalised for alcoholic weaning; with an alcoholic liver disease; with at risk alcoholic consumption; with an indication of liver biopsy; with a signed consentment.

Exclusion Criteria:

- patients with a cirrhosis; with other causes of liver disease; with a contraindication of liver biopsy; having had a liver biopsy in the last 3 years; pregnancy; major benefiting from a legal protective measure; no coverage care.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01789008

Contacts

Contact: Romain Moirand, MD, PhD 02 99 28 42 97 romain.moirand@univ-rennes1.fr

Locations

France

Rennes university hospital **Recruiting**
Rennes, France, 35000
Contact: Romain Moirand, MD, PhD 02 99 28 42 97 romain.moirand@univ-rennes1.fr
Principal Investigator: Romain Moirand, Md, PhD

Sponsors and Collaborators

Rennes University Hospital

More Information

No publications provided

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ClinicalTrials.gov Identifier:	NCT01789008 History of Changes
Other Study ID Numbers:	PHRC/12-01 2012-A01171-42
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Health Authority:	France: Agence Nationale de Sécurité du Médicament et des produits de santé

Keywords provided by Rennes University Hospital:
Transient elastography
Alcoholic liver disease
liver fibrosis

Additional relevant MeSH terms:
Fibrosis
Liver Diseases
Liver Diseases, Alcoholic
Alcohol-Induced Disorders
Alcohol-Related Disorders
Chemically-Induced Disorders
Digestive System Diseases
Pathologic Processes
Substance-Related Disorders

ClinicalTrials.gov processed this record on February 07, 2016

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