# Methacetin breath test in patients with cirrhosis

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
17/02/2017		<pre>Protocol</pre>		
Registration date	Overall study status	<ul><li>Statistical analysis plan</li></ul>		
02/03/2017	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
09/08/2018	Digestive System			

#### Plain English summary of protocol

Background and study aims

Cirrhosis is a serious complication of liver disease, which involves widespread scarring of the liver. The damage to the liver caused by cirrhosis means that eventually the liver is unable to fulfil its normal functions, ultimately leading to liver failure. Cirrhosis develops gradually, however the damage to the liver is irreversible, and gets worse over time. The Child-Pugh score (CP score) is a test that evaluates give clinical features in order to assess the prognosis (likely course) of cirrhosis. It is commonly used, however it isn't always accurate as it relies heavily on interpretation. 13C-phenylalanine and 13C-methacetin tests are breath tests which can be used to accurately measure how well the liver is functioning, and therefore if cirrhosis is worsening. The aim of this study is to find out whether the 13C-methacetin test can be used to predict long-term survival of patients with cirrhosis.

Who can participate?

Adults who have been diagnosed with cirrhosis.

#### What does the study involve?

Patients undergo a complete clinical assessment which involves testing their liver function using standard tests for liver function (CP score) and the 13C-methacetin test. This involves the collection of repeated breath samples after the patient has ingested 75 mg 13C-methacetin dissolved in water. The results are then used to predict the likely course of the disease for each patient. Participants are followed up for three years, at least once every six months at routine hospital appointments to assess survival rates and if the disease has worsened.

What are the possible benefits and risks of participating? There are no notable benefits or risks involved with participating.

Where is the study run from?
National Medical Center XXI Century (Mexico)

When is the study starting and how long is it expected to run for? June 2008 to December 2016

Who is funding the study?

- 1. Mexican National Council for Science and Technology (Mexico)
- 2. Health Research Council of Mexican Institute of Social Securite (Mexico)

Who is the main contact? Dr Segundo Morán

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Segundo Morán

#### **ORCID ID**

https://orcid.org/0000-0001-6833-2392

#### Contact details

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# Additional identifiers

#### Protocol serial number

R-2008-3601-4

# Study information

#### Scientific Title

Utility of 13C-methacetin breath test in predicting long-term survival of patients with decompensated cirrhosis

# **Study objectives**

13C-methacetin breath test (13C-MeBT) can predict a long-term survival in patients with decompensated cirrhosis.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Ethics Committee and Investigation Review Board at Centro Medico Nacional Siglo XXI, Mexican Institute of Social Security, 12/06/2008, ref: R-2008-3601-4

# Study design

#### Observational cohort study

#### Primary study design

Observational

#### Study type(s)

Screening

## Health condition(s) or problem(s) studied

Cirrhosis

#### **Interventions**

Consecutive patients with decompensated cirrhosis are studied at the Laboratory of Gastro-Hepatology of Centro Medico Nacional Siglo XXI. Diagnosis of decompensated cirrhosis based on history of present illness, clinical and biochemical findings combined with ultrasonographic results, plus liver biopsy when possible.

All patients are studied following the same protocol with data collected by the laboratory staff and were followed either as outpatients or inpatients when necessary. Hepatic function is evaluated by 13C-MeBT and standard liver blood tests. The clinical diagnosis and degree of encephalopathy is determined according to the West-Haven criteria. Observation begins the day that the patient is admitted to the study, defined as "zero time" (t0). Patients are followed-up at least every 6 months for up to 3 years. Death is recorded during the three years of follow-up.

#### Intervention Type

Other

### Primary outcome(s)

- 1. Survival is assessed through patient follow ups at least every 6 months for up to 3 years with analysis performed by the Kaplan-Meier method
- 2. The optimal cut-off point for predicting mortality to base line 13C-MetOx obtained by 13C-methacetin breath test within 3 years

# Key secondary outcome(s))

The optimal cut-off point for predicting mortality to base line Child-Pugh (CP) and Meld Indexes within 3 years.

# Completion date

17/12/2016

# Eligibility

## Key inclusion criteria

- 1. Age above 18 years
- 2. Diagnosis of decompensated cirrhosis based on history of present illness, clinical and biochemical findings combined with ultrasonographic results, plus liver biopsy when possible

# Participant type(s)

Patient

## Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

#### Sex

All

# Key exclusion criteria

Hepatocarcinoma

#### Date of first enrolment

01/01/2009

#### Date of final enrolment

17/12/2014

# **Locations**

#### Countries of recruitment

Mexico

# Study participating centre National Medical Center XXI Century

Cuauhtémoc 330 Colonia Doctores Mexico Mexico 06725

# Sponsor information

## Organisation

Health Research Council of Mexican Institute of Social Security

#### **ROR**

https://ror.org/03xddgg98

# Funder(s)

# Funder type

Research council

#### Funder Name

Mexican National Council for Science and Technology

#### Funder Name

Health Research Council of Mexican Institute of Social Securite

# **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Segundo Moran MD (segundomoran@hotmail.com)

# IPD sharing plan summary

Available on request

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/09/2017		Yes	No