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Methacetin breath test in patients with cirrhosis

Submission date	Recruitment status	[_] Prospectively registered
17/02/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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 measure
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

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

Overall study start date

12/06/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
123 patients

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
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Sponsor information

Organisation
Health Research Council of Mexican Institute of Social Security

Sponsor details
Cuauhtemoc 330
Colonia Doctores
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Sponsor type
Research council

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

Publication and dissemination plan
Planned publication in a peer reviewed journal with an impact factor.

Intention to publish date
31/12/2017

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