ISRCTN45415158 https://doi.org/10.1186/ISRCTN45415158

Breath test for patients with acute liver disease for early detection of the need for transplant or recovery

Submission date 27/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/02/2010	**Overall study status** Completed	
Last Edited 11/04/2019	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Julia Wendon

Contact details
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01435421

Secondary identifying numbers
ALF-BID-1108

Study information

Scientific Title
Breath test for patients with acute liver disease for early detection of the need for transplant or recovery: a multicentre non-randomised study

Acronym
BTALD (Breath Test in Acute Liver Disease)

Study objectives
This study is designed to develop a model to predict deterioration of liver disease, which incorporates measurements from the 13C-Methacetin Breath Test (MBT) along with other potential variables. The data collected will be used to develop a prediction model using data-mining methodology (linear and non-linear regression models, binary trees, neural networks, etc.,). The predictive models may include measurements from the MBT and blood test results as single measurements or as a trend over time. The model that will be developed will attempt to predict the disease deterioration versus recovery accurately, at an earlier time point than the standard procedure. A threshold will then be determined based on adequate sensitivity and specificity levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee approved on the 21/10/2009, ref: 09/H1102/62

Study design
Multicentre non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute liver failure

Interventions

This is a study of the MBT to assess liver function in patients with acute and/or chronic liver injury. All patients with acute liver disease meeting the inclusion/exclusion criteria will be accepted to this study. Patients will perform up to 7 tests; these may be performed in the course of a 21-day period, including days 0, 2, 4, 6, 10, 14, and 21.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To develop a model to predict deterioration of liver disease, which incorporates measurements from the MBT along with other potential variables. Tests will be performed in the course of a 21-day period or discontinued when the patient is discharged from hospital or if transplantation is undertaken or the patients' ongoing care is deemed futile and palliative care is being undertaken.

Secondary outcome measures
Safety evaluation through assessment of BreathID system (device and drug) related adverse events. Tests will be performed in the course of a 21-day period or discontinued when the patient is discharged from hospital or if transplantation is undertaken or the patients' ongoing care is deemed futile and palliative care is being undertaken.

Overall study start date
02/11/2009

Completion date
30/10/2011

Eligibility

Key inclusion criteria
1. Adult men or women (greater than 18 years of age)
2. Acute liver insult
3. No evidence of cirrhosis (unless clinical acute Wilsons)
4. International Normalised Ratio (INR) greater than 1.8
5. Duration of illness less than 12 or 24 weeks (to be determined [TBD])

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
30

Key exclusion criteria
1. Any chronic liver disease
2. Severe congestive heart failure
3. Severe pulmonary hypertension
4. Chronic renal insufficiency with severe cardiac disease
5. Previous surgical bypass surgery for morbid obesity
6. Extensive small bowel resection
7. Any autoimmune disorder, which is currently being treated with prednisone or any other immune suppressive medication
8. Recipient of any organ transplant
9. Proven or suspected hepatocellular carcinoma
10. Pregnant
11. Allergic to paracetamol (such as Tylenol® or any other related medications)
12. History of chronic obstructive pulmonary disease or symptomatic bronchial asthma
13. Septic cholestasis
14. Currently receiving total parenteral nutrition if they have contraindications to oral drugs
15. Taking hepatotoxin drugs
16. Hypersensitivity to paracetamol
17. Based on the opinion of the investigator, patient should not be enrolled into this study
18. Unable or unwilling to sign informed consent
19. Participating in other clinical trials evaluating experimental treatments or procedures

Date of first enrolment
02/11/2009

Date of final enrolment
30/10/2011

Locations

Countries of recruitment
England

Israel

United Kingdom

United States of America

Study participating centre
King's College Hospital
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
Exalenz Bioscience Ltd (Israel)

Sponsor details
c/o Steven Eitan
4 Maayan
Modi'in
Israel
71700

Sponsor type
Industry

ROR
https://ror.org/04e29rd57

Funder(s)

Funder type
Industry

Funder Name
Exalenz Bioscience Ltd (Israel)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/03/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	conference abstract	01/10/2012	08/03/2019	No	No
HRA research summary			28/06/2023	No	No