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Bone marrow stem cell transplantation in patients with decompensated liver cirrhosis

Submission date 01/04/2015	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 15/04/2015	**Overall study status** Completed	
Last Edited 17/04/2015	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
The treatment of patients with advanced liver disease (decompensated liver cirrhosis) is very challenging. Stem cell therapy is one treatment being developed to repair damaged tissues or organs in patients using their own cells. Stem cells are found in various parts of the body, such as bone marrow, and they are important in repairing damage and maintaining healthy cells. In this study, bone marrow stem cells are taken from patients, processed and then transplanted back into patients' bodies to help repair their damaged liver. The aim is to improve patient health and provide an in-between treatment before liver transplantation.

Who can participate?
Patients with advanced decompensated liver cirrhosis caused by chronic viral hepatitis B or C.

What does the study involve?
Bone marrow stem cells are taken from the side of the hip bone while the patient is under local anaesthetic. Patients are later injected with their own processed cells into an artery through a catheter. A follow-up visit takes place 12 months after stem cell transplantation which includes a blood test for liver function and health questionnaires.

What are the possible benefits and risks of participating?
Participants may show improved liver function following treatment with stem cells. There is a risk of mild pain at injection sites.

Where is the study run from?
N. Kipshidze Central University Hospital (Georgia)

When is the study starting and how long is it expected to run for?
February 2011 to October 2014

Who is funding the study?
N. Kipshidze Central University Hospital (Georgia)

Who is the main contact?
Prof Z Kakabadze (Georgia)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Autologous bone marrow stem cell transplantation in patients with decompensated liver cirrhosis: results from first in man study

Study objectives
Our aim is to evaluate the safety and feasibility of autologous bone marrow mesenchymal stem cell (BMC) transplantation in patients with decompensated liver cirrhosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Central University Hospital, Tbilisi, Georgia, 10/12/2010, ref: 3.

Study design
Interventional non-randomized controlled study with two study branches.

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Decompensated liver cirrhosis

Interventions
1. 50-100 mL of bone marrow was aspirated from the anterior iliac crest under local anesthesia
2. At least 100 million of enriched mononuclear cells was infused into the hepatic artery of the patients through a catheter for 20 minutes, using a routine technique similar to arterial chemoembolization of liver tumors

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Liver function (blood) test
2. Model for End-Stage Liver Disease (MELD) score
3. Child-Pugh Score for cirrhosis mortality

Secondary outcome measures
Cirrhosis mortality

Overall study start date
10/02/2011

Completion date
15/10/2014

Eligibility

Key inclusion criteria

1. Chronic hepatic failure
2. Ultrasonographic evidences of cirrhosis and portal hypertension
3. Child-Pough class B and C score
4. Patients must have the ability to sign the informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
34

Key exclusion criteria
1. Patients aged less than 18 or more than 70
2. Hepatopulmonary syndrome
3. Documented hepatocellular carcinoma or history of other cancer
4. Presence of hepatic, portal or splenic vein thrombosis on doppler ultrasonography
5. History of autoimmune diseases
6. Use of hepatotoxic drugs within the last 6 month before enrolment
7. Decompensated heart failure
8. Renal failure (creatinine >2.5 mg/dL)
9. International normalized ratio (INR) >2.2
10. Patients with acute infection
11. Patients with pregnancy or lactation
12. Patients with recurrent gastrointestinal bleeding
13. Patients with spontaneous bacterial peritonitis
14. Patients unable to give informed consent

Date of first enrolment
10/02/2011

Date of final enrolment
12/04/2014

Locations

Countries of recruitment
Georgia

Study participating centre
N. Kipshidze Central University Hospital
29 Vazha-Pshavela Avenue
Tbilisi

Georgia
0177

Sponsor information

Organisation
N. Kipshidze Central University Hospital (Georgia)

Sponsor details
Vazha-Pshavela Ave.#29
Tbilisi
Georgia
0177

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/020jbrt22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
N. Kipshidze Central University Hospital (Georgia)

Results and Publications

Publication and dissemination plan

Intention to publish date
01/09/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request