

# Bone marrow stem cell transplantation in patients with decompensated liver cirrhosis

<b>Submission date</b> 01/04/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/04/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/04/2015	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

Cirrhosis mortality

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

**ROR**

<https://ror.org/020jbrt22>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

N. Kipshidze Central University Hospital (Georgia)

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request