

Repeated autologous infusions of stem cells in cirrhosis

Submission date 28/04/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 18/11/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 13/11/2017	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Phil Newsome

Contact details
Centre for Liver Research
Institute of Biomedical Research
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Additional identifiers

Protocol serial number
RRK3728/HE2012

Study information

Scientific Title
A multicentre, phase II, open-label, randomised controlled trial of repeated autologous infusions of granulocyte colony stimulating factor (GCSF) mobilised CD133+ bone marrow stem cells in patients with cirrhosis

Acronym

REALISTIC

Study objectives

Animal data suggests that haematopoietic stem cells (HSCs) and granulocyte colony stimulating factor (GCSF) play an important role in increasing hepatic regeneration and reducing hepatic fibrosis. This study aims to demonstrate the superiority of either GCSF alone or GCSF followed by repeated infusions of HSCs (CD133+ bone marrow stem cells) over standard conservative management in improving severity of liver disease over three months.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Submitted to Oxfordshire Research Ethics Committee A, decision due May 2009

Primary study design

Interventional

Study design

Multicentre phase II open-label randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Liver cirrhosis

Interventions

Trial Group 1: Standard conservative management

Trial Group 2: GCSF (Lenograstim) 15 µg/kg subcutaneously daily for 5 days

Trial Group 3: GCSF (Lenograstim) 15 µg/kg subcutaneously daily for 5 days, followed by leukapheresis, isolation of CD133+ cells and reinfusion on day 6, day 30 and day 60.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Granulocyte colony stimulating factor (GCSF) (Lenograstim)

Primary outcome(s)

Change in MELD score (delta MELD) from baseline (day 0) to day 90

Key secondary outcome(s)

1. Changes from baseline to day 90, day 180 and day 360 in:

1.1. Enhanced Liver Fibrosis (ELF) score

1.2. Transient elastography (Fibroscan)

- 1.3. United Kingdom End stage Liver Disease (UKELD) score
 - 1.4. Chronic Liver Disease Questionnaire (CLDQ) - quality of life score
 - 1.5. Individual blood parameters
 - 1.6. Clinical events
 - 1.7. Transplant-free survival
-
2. Changes from baseline to day 5 in:
 - 2.1. Circulating CD34+ cells
 - 2.2. Circulating CD133+ cells

Completion date

01/07/2013

Eligibility

Key inclusion criteria

1. Both males and females, age 18 - 70 years
2. Model for End stage Liver Disease (MELD) score 12 - 15
3. Aetiology of liver disease, one or more of:
 - 3.1. Alcohol related liver disease
 - 3.2. Hepatitis C
 - 3.3. Hepatitis B
 - 3.4. Primary biliary cirrhosis
 - 3.5. Non-alcoholic fatty liver disease
 - 3.6. Cryptogenic cirrhosis
 - 3.7. Haemachromatosis
4. Cirrhosis (invasive or non-invasive diagnosis)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Inability or refusal to give informed consent
2. Alcohol consumption within recommended limits
3. Uncontrolled ascites
4. Encephalopathy in last 6 months
5. Portal hypertensive bleeding in last 6 months
6. Current or previous hepatocellular carcinoma (including dysplastic nodules)

7. Previous liver transplant
8. Listed for liver transplantation
9. Pregnancy or breastfeeding

Date of first enrolment

01/07/2009

Date of final enrolment

01/07/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Birmingham

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University Hospitals Birmingham NHS Foundation Trust (UK)

ROR

<https://ror.org/014ja3n03>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Biomedical Research Unit Birmingham

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Sir Jules Thorn Charitable Trust

Alternative Name(s)

The Sir Jules Thorn Charitable Trust

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

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?
Results article	results	01/01/2018		Yes	No
Protocol article	protocol	20/03/2015		Yes	No