ISRCTN91288089 https://doi.org/10.1186/ISRCTN91288089

Repeated autologous infusions of stem cells in cirrhosis

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Committe A, decision due May 2009

Study design
Multicentre phase II open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Secondary outcome measures
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

Overall study start date
01/07/2009

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
81

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
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust (UK)

Sponsor details
Research and Development Department
4th Floor Nuffield House
Queen Elizabeth Hospital
Birmingham
England
United Kingdom
B15 2TH

Sponsor type
Hospital/treatment centre

Website
http://www.uhb.nhs.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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