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A review study to evaluate mannitol-assisted prophylaxis and treatment for acute promyelocytic leukemia

Submission date
14/12/2013

Recruitment status
No longer recruiting

Registration date
20/01/2014

Overall study status
Completed

Last Edited
26/06/2014

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In acute promyelocytic leukemia (APL), central nervous system (CNS) relapse occurs due to a lack of sufficient medication in the brain. The aim of our study is to enrol medium to high risk APL patients and patients with APL CNS relapse and to study whether mannitol-assisted prophylaxis (protective treatment) helps drugs penetrate the blood-brain barrier, thereby increasing the amount of the drugs in the CNS.

Who can participate?
Any APL patients (all age groups) at risk of CNS relapse or diagnosed with CNS relapse.

What does the study involve?
Our mannitol-assisted treatment strategy includes intravenous infusion (i.e., administered into a vein) of mannitol and arsenic trioxide (ATO). Patients at risk of CNS relapse will receive prophylaxis of mannitol and ATO; patients who have been diagnosed with CNS relapse will receive intrathecal chemotherapy (i.e., administered into the spine) plus mannitol and ATO. Long-term follow-up of the patients will be carried out.

What are the possible benefits and risks of participating?
Benefits are expected for the patients who will receive mannitol-assisted prophylaxis or treatment. Mannitol should help the ATO cross the blood-brain barrier, thereby increasing the amount of the drug in the CNS. The main risk of giving mannitol is to decrease the cerebral pressure (the pressure inside the skull). This could be prevented by letting the patients lie down for at least 10 hours during and after treatment.

Where is the study run from?
The study was set up at the First Affiliated Hospital of Harbin Medical University (China).

When is the study starting and how long is it expected to run for?
This study started in 1998 and is expected to run until 2018.

Who is funding the study?
China National Natural Science Foundation and China 863 Projects Foundation.

Who is the main contact?
Professor Jin Zhou, jinzhouh85@163.com
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
97-01-CHN

Study information

Scientific Title
Retrospective study on mannitol-assisted prophylaxis and treatment for acute promyelocytic leukemia

Study objectives
It was hypothesized that mannitol could help drugs enter the blood brain barrier (BBB). Thereby it could improve the clinical outcome of acute promyelocytic leukemia (APL) patients during prophylaxis and treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Harbin Medical University Ethics Committee, 16/10/1997, ref: HM970018

Study design
Retrospective study of a treatment's long-term outcome

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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
APL CNS relapse

Interventions
The study involved two groups of APL patients receiving different mannitol-assisted regimens:
1. Patients with CNS relapse received intrathecal chemotherapy plus mannitol-assisted arsenic trioxide (ATO)
2. Patients at risk of CNS relapse received mannitol-assisted ATO prophylaxis

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mannitol, arsenic trioxide

Primary outcome measure
1. Disease-free survival
2. Overall survival

Secondary outcome measures
1. Cerebrospinal fluid (CSF) ATO concentrations
2. CSF tests of APL burden
3. Drug side effects evaluation

Overall study start date

01/01/1998

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Any age APL patients, with either risks of central nervous system (CNS) relapse or already diagnosed with CNS relapse
2. Patients agreed to receive the prophylaxis or treatment

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Previous history of severe cardiovascular disease (coronary arterial disease, stroke, etc)
2. Severe chronic disease with poor prognosis (liver disease, kidney disease, etc)
3. Illegal drug use or chronic alcoholism
4. Physical limitations, mental or intellectual disabilities
5. Any condition that may affect the development of this trial

Date of first enrolment
01/01/1998

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
China

Study participating centre
First Affiliated Hospital of Harbin Medical University
Harbin
China
150001

Sponsor information

Organisation
First Affiliated Hospital of Harbin Medical University (China)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05vy2sc54

Funder(s)

Funder type
Government

Funder Name
China National Natural Science Foundation (China), No. 81070439

Funder Name
China 863 Projects Foundation (China), No. 2012AA020903

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?
Results article	results	18/09/2014		Yes	No