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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
14/12/2013		□ Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/01/2014	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
26/06/2014	Cancer			

#### 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. Longterm 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 Professor Hong Wang, wh557@yahoo.com

# **Contact information**

#### Type(s)

Scientific

#### Contact name

Dr Jin Zhou

#### Contact details

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# Additional identifiers

#### Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

- 1. Disease-free survival
- 2. Overall survival

#### Key secondary outcome(s))

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

#### 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

#### Healthy volunteers allowed

No

#### Age group

#### Other

#### Sex

All

#### 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)

#### **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**

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes