

# To evaluate chemotherapy and decitabine treatment for acute myeloid leukemia

|                                        |                                                   |                                                                                                              |
|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>07/10/2014   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>23/10/2014 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>23/10/2014       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims:

Leukaemia is a cancer of the white blood cells. Acute myeloid leukaemia (AML) is an aggressive cancer of the myeloid cells, white blood cells that perform a variety of functions, including fighting bacterial infections and parasites. It progresses rapidly and needs immediate treatment. The prognosis for someone with AML is usually poor, as the chemotherapy used is often insufficient to successfully treat the condition. Decitabine is one of a new class of chemotherapy drugs called DNA demethylating agents. DNA methylation is a major mechanism that regulates gene expression in cells and an increase in DNA methylation can block the activity of tumour suppressor genes that control cell division and growth. Blocking the activity of these suppressor genes can result in cell division that is not controlled, which in turn, can lead to cancer. Decitabine works in two ways. It interferes with DNA methylation (demethylating), which causes the tumour suppressor genes to become active again and restore control over cell division and growth. Decitabine is also very toxic to rapidly dividing cancer cells, causing cell death. Here, we want to see if decitabine assisted chemotherapy could be an effective treatment for AML.

### Who can participate?

Any AML patients (except acute promyelocytic leukaemia (APL) patients) of any age that have relapsed, or are considered at risk of relapse.

### What does the study involve?

Participants are treated with decitabine combined with chemotherapeutic drugs (anthracycline, cytarabine, etc.). Each patient is treated for a maximum of 5 years and they are followed up once every 3 months until their death or after a further period of 5 years.

### What are the possible benefits and risks of participating?

There are great benefits expected for patients who receive decitabine assisted chemotherapy in terms of being treated for AML. The main risks are bleeding and flu like symptoms. This can be prevented by reducing the dose given and using alternative drugs during the treatment schedule.

### Where is the study run from?

First Affiliated Hospital of Harbin Medical University (China)

When is the study starting and how long is it expected to run for?  
January 2007 to December 2019

Who is funding the study?  
1. China National Natural Science Foundation (China)  
2. China 863 Projects Foundation (China)

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**  
Department of Hematology  
First Affiliated Hospital  
Harbin Medical University  
Harbin  
China  
150001  
+86 (0) 451 53641824  
zhoujin1111@126.com

## Additional identifiers

**Protocol serial number**  
2007-11-CHN

## Study information

**Scientific Title**  
Perspective study on an effective treatment for acute myeloid leukemia with decitabine and chemotherapy

**Study objectives**  
It was hypothesized that decitabine with low-dose chemotherapy function synergistically. Thereby together they could improve the clinical outcome of acute myeloid leukemia (AML) patients (except acute promyelocytic leukemia [APL]) during the treatment.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Harbin Medical University Ethics Committee, 12/12/2006, ref: HM070110.

**Primary study design**

Interventional

**Study design**

Perspective study of a treatment's long-term outcome

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Acute myeloid leukemia (AML)

**Interventions**

The study involved AML patients (except APL patients) from different Hematology departments in different hospitals at Heilongjiang Province in China. All the treatment centers follow the same treatment protocol and evaluation standards.

Treatment methods: AML patients who give written consent to accept the treatment protocols are enrolled. For remission induction, each cycle of treatment includes cytarabine 100 mg/m<sup>2</sup> for 7 days, anthracycline 15 mg/m<sup>2</sup> for another 3 days, decitabine 10-15 mg/m<sup>2</sup> once every 2 days. Five treatment cycles are repeated with 2-week intervals after the first cycle. For maintenance treatment, treatment is repeated once every three months. Blood and bone marrow cell study, biopsy, and cytogenetics are tested once every 3 months.

The total duration of treatment is 5 years, and follow-up for all treatment arms is from diagnosis, then once every 3 months, until death or 5 years and beyond.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Patient disease-free survival and overall survival

**Key secondary outcome(s)**

1. Patient drug concentrations
2. Patient AML burden during each treatment period
3. Drug side effects evaluation
4. Patient relapse-free survival
5. Patient overall survival

To monitor the primary and secondary clinical outcomes, patients' peripheral blood and bone marrow samples were tested at diagnosis, and at the end of each treatment cycle: blood cell count and staining, flow cytometry, RT-PCR and in-situ hybridization are used to test cell morphology, gene mutations, and cytogenetic changes.

**Completion date**

31/12/2019

## Eligibility

**Key inclusion criteria**

1. Any age AML patients (except APL) at different treatment stages, who are responsive or non-responsive to conventional treatments are all included in this trial
2. Patients agreed to receive the 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**

01/01/2007

**Date of final enrolment**

31/12/2019

## Locations

**Countries of recruitment**

China

**Study participating centre****Department of Hematology**

Harbin

China

150001

# Sponsor information

## Organisation

Heilongjiang Institute for Hematology and Oncology Research (China)

## Funder(s)

### Funder type

Government

### Funder Name

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

### Funder Name

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

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration