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To evaluate chemotherapy and decitabine treatment for acute myeloid leukemia

Submission date 07/10/2014	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 23/10/2014	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 23/10/2014	**Condition category** Cancer	[ ] Individual participant data [ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

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

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
The patient information sheets are available at the First Affiliated Hospital at Harbin Medical University

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/m2 for 7 days, anthrocycline 15 mg/m2 for another 3 days, decitabine 10-15 mg/m2 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 measure
Patient disease-free survival and overall survival

Secondary outcome measures
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.

Overall study start date
01/01/2007

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

Age group
Other

Sex
Both

Target number of participants
3000

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
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Sponsor information

Organisation
Heilongjiang Institute for Hematology and Oncology Research (China)

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Sponsor type
Hospital/treatment centre

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

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