

Treatment with cytokine induced killer cells for leukaemia patients

Submission date 05/09/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 18/09/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/10/2020	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Cytokine-induced killer cells or CIK cells are a type of immune system cell that can be grown from a patient's own cells in the lab and then given back to the patient to kill cancer cells. CIK treatment could be used to treat patients with leukemia (cancer of the white blood cells). The aim of this study is to find out whether CIK treatment improves the disease outcome of leukemia patients and reduces the number of chemotherapy cycles required.

Who can participate?

Patients aged between 5 and 60 with leukemia

What does the study involve?

Participants are treated with either standard chemotherapy or chemotherapy combined with CIK treatment. Their clinical outcome is closely monitored with prompt supportive treatment and relapse prevention treatment. Whole body PET/CT scans are used to monitor disease development. At the end of the study, the relapse-free period and overall survival rates are compared among different age groups, leukemia types and treatment strategies.

What are the possible benefits and risks of participating?

This study should help to improve the well-being of leukemia patients in China. Immediate direct benefits are expected to be observed with CIK treatment. The side effects of chemotherapy would be reduced with the use of CIK treatment. The long-term tumor-killing effects of CIK cells remain unknown and are likely to be vary by person. The main risk of giving CIK cells to leukemia patients is infection from contamination of cultured blood products. Therefore, good manufacturing practice conditions are strictly followed. Participants are closely monitored during treatment.

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 2011 to December 2017

Who is funding the study?

1. National Natural Science Foundation (China)
2. 863-Program in the "Eleventh Five" (China)
3. Science and Technology Platform in Heilongjiang (China)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

81070439

Study information

Scientific Title

Consecutive autologous cytokine induced killer cell infusion for haematological malignancies and positron emission tomography (PET) scanning

Study objectives

A consecutive autologous cytokine induced killer (CIK) cell infusion combined with chemotherapy, applied to hematological malignancy patients reduces the incidence of chemotherapy complications, improves prognosis with PET/computerised tomography (CT) scan evaluation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Primary study design

Interventional

Study design

Randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hematological malignancies

Interventions

Participants are volunteered to be divided into two groups.

1. Standard chemotherapy
2. Chemotherapy combined with autologous CIK infusion

Intervention Type

Mixed

Primary outcome(s)

1. Outcome of leukemia after CIK treatment at short-term follow up: 1 month, 3 months, 6 months and 1 year
2. Remission or relapse evaluation at long-term follow up: 1 year, 2 years, 3 years, 4 years and 5 years (end of study)

Key secondary outcome(s)

1. Age, white blood cell (WBC) count, platelet count, hemoglobin (Hb) level, percentage of leukemia cells in bone marrow and absolute number in peripheral blood. Karyotypic findings with cytogenetic markers
 2. Type of treatment, number of treatment cycles to achieve remission
 3. Minimal residual disease evaluation with whole body PET/CT scan, in-vivo CIK cell function sites with FDG labeling PET/CT scan
- Measured at diagnosis, short-term and long-term follow up after treatment

Completion date

15/12/2017

Eligibility

Key inclusion criteria

1. Community-dwelling leukemia patients
2. 5 to 60 years old, who would volunteer to accept autologous CIK cell treatment
3. Volunteer to accept chemotherapy but reject autologous CIK cell treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Total final enrolment

9

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

01/01/2011

Date of final enrolment

31/12/2015

Locations

Countries of recruitment

China

Study participating centre

Harbin Medical University First Affiliated Hospital

Harbin

China

150001

Sponsor information

Organisation

Harbin Medical University First Affiliated Hospital (China)

ROR

<https://ror.org/05vy2sc54>

Funder(s)

Funder type

Research organisation

Funder Name

National Natural Science Foundation of China ref: 81070439

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Funder Name

863 - Program in the "Eleventh Five" (China) ref: 2012AA020903

Funder Name

Science and Technology Platform, Heilongjiang (China) ref: PG09J003

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014	23/10/2020	Yes	No