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Treatment with cytokine induced killer cells for leukaemia patients

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

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

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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)

Ethics and Health Research Committee of Hematology and Oncology, Heilongjiang, China, 08/06/2010, ref: 81070439

Study design
Randomized controlled trial

Primary study design
Interventional

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