

A phase I trial of allogeneic tumour-activated natural killer lymphocytes for the treatment of selected patients with acute myeloid leukaemia.

Submission date 28/11/2014	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 17/12/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/03/2019	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/trials/a-trial-looking-at-an-infusion-of-natural-killer-cells-after-chemotherapy-and-radiotherapy-for-acute-myeloid-leukaemia>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2005-006087-62

Protocol serial number

REC 7654

Study information

Scientific Title

A phase I trial of allogeneic tumour-activated natural killer lymphocytes after low dose TBI and fludarabine for the treatment of selected patients with acute myeloid leukaemia.

Acronym

TaNK in AML

Study objectives

Donor natural killer (NK) cells activated by tumour cells can be safely infused into a patient with acute myeloid leukaemia

Ethics approval required

Old ethics approval format

Ethics approval(s)

UK National Patient Safety Agency National Research Ethics Service, 27/11/2007, ref. Royal Free Hospital LREC 7654

Primary study design

Interventional

Study design

Single-center non-randomised open-label phase I safety study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patients with acute myeloid leukaemia

Interventions

A single skin biopsy will be taken at time of Hickman Line insertion from the surgical site. Each patient will receive five days of Fludarabine followed by one dose of single fraction total body irradiation. Monthly 20ml peripheral blood samples will be taken from day +30 until day + 180. Each patient will receive a single infusion of the IMP.

Intervention Type

Biological/Vaccine

Phase

Phase I

Primary outcome(s)

To determine the safety of infusion of allogeneic, tumour-activated NK cells after low dose radiotherapy plus medium dose chemotherapy with respect to acute / chronic GvHD and bone marrow suppression

Key secondary outcome(s)

1. To assess the quantitative and qualitative aspects of immune responses to acute myeloid leukaemia (AML) cells in these patients after NK cell infusion
2. To assess long term survival of donor NK cells in the peripheral circulation of recipients

Completion date

01/03/2011

Eligibility**Key inclusion criteria**

All recipients will have a diagnosis of acute myeloid leukaemia (AML) and be in one of the following subgroups:

1. Patients aged > 60 years in PR (blasts >5<20% in BM) after 2nd course of induction chemotherapy
2. Patients aged > 60 years with relapsed AML in CR2 after re-induction chemotherapy
3. Patients aged > 60 years in PR or CR after 2 courses of chemotherapy with poor risk disease using standard MRC criteria
4. Patients aged < 60 years beyond CR2 who are not suitable for stem cell transplantation with conventional or reduced intensity conditioning protocols

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. HIV 1-2 seropositive
2. Psychiatric, addictive, or any disorder which compromises ability to give true informed consent for participation in this study
3. Pregnant or lactating women
4. Patients whose life expectancy is severely limited by illness other than for which they are undergoing immunotherapy
5. Patients with other active malignancy
6. Patients with known physical or religious sensitivity or prior exposure to murine and/or ovine proteins

Date of first enrolment

01/07/2007

Date of final enrolment

01/03/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal Free Hospital

London

United Kingdom

NW3 2QG

Sponsor information

Organisation

University College London

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

Leukaemia Research Fund (UK)

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				

[Results article](#)

10/06/2015

Yes

No