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

| Submission date   | Recruitment status   | <ul><li>Prospectively registered</li></ul> |
|-------------------|----------------------|--|
| 28/11/2014        | No longer recruiting | <pre>Protocol</pre>                        |
| Registration date | Overall study status | Statistical analysis plan                  |
| 17/12/2014        | Completed            | [X] Results                                |
| Last Edited       | Condition category   | [] Individual participant data             |
| 01/03/2019        | Cancer               |  |

## 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

#### Study design

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

#### Primary study design

Interventional

# 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** results

Date created Date added Peer reviewed? Patient-facing?

Results article 10/06/2015 Yes No

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