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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/12/2014	**Overall study status** Completed	
Last Edited 01/03/2019	**Condition category** 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

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Additional identifiers

EudraCT/CTIS number
2005-006087-62

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2007

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

Age group
Adult

Sex
Both

Target number of participants
15

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
England

United Kingdom

Study participating centre
Royal Free Hospital
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
University College London

Sponsor details
Gower Street
London
United Kingdom
WC1N

Sponsor type
University/education

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Leukaemia Research Fund (UK)

Results and Publications

Publication and dissemination plan

Intention to publish date

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	10/06/2015		Yes	No