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Development of activated natural killer (NK) cells mediated immunotherapy in cancer

Submission date	Recruitment status	[ ] Prospectively registered
15/07/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/08/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/08/2011	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Research for the effect of biological response modifiers (BRMs) on natural killer (NK) cell cytotoxicity

Study objectives
Natural killer (NK) cells play an important role in innate immune response by destroying tumours and virus-infected cells without prior stimulation. Because of their attractive features, the application of NK cell-based immunotherapy has been extended to cancer treatment. This study investigates the function of biological response modifiers (BRMs) on NK cell cytotoxicity and the effect of NK cell mediated immunotherapy in cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Samsung Medical Centre Institutional Review Board. Date of approval: 18/03/2008 (ref: 2008-03-038)

Study design
Single-centre, observational study

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Other

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
Immunotherapy in cancer

Interventions
A blood sample will be obtained from each participant. A variety of BRMs (small synthetic peptides, interleukins, natural extracts) will be tested on the blood samples to measure their effect on NK cell cytotoxicity. This will be measured using established assays such as carboxyfluorescein diacetate succinimidylester (CFSE). The BRMs that show high levels of NK cell cytotoxicity will have the potential for use in cancer treatment.

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Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. To find BRMs that lead to the highest levels of NK cell cytotoxicity in the treated blood samples
2. To find the optimum dose and duration of treatment with the BRMs found to elicit highest levels of NK cell cytotoxicity

Secondary outcome measures
Gene expression profiles associated with peripheral blood lymphocyte (PBL) cytotoxicity and related mechanisms in the blood samples.

Overall study start date
01/05/2008

Completion date
30/04/2010

Eligibility

Key inclusion criteria
1. Healthy volunteers aged 18 years or older, both males and females
2. Written informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Aged less than 18 years
2. Those who do not speak Korean

Date of first enrolment
01/05/2008

Date of final enrolment
30/04/2010

Locations

Countries of recruitment
Korea, South

Study participating centre
Department of Life Sciences
Seoul
Korea, South
140-742

Sponsor information

Organisation
Sookmyung Women's University (Korea, South)

Sponsor details
Hyochangwon-gil 52
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Sponsor type
University/education

Website
http://www.sookmyung.ac.kr

ROR
https://ror.org/00vvvt117

Funder(s)

Funder type
Government

Funder Name
Korea Health Industry Development Institute (KHIDI) (ref: A080363)

Alternative Name(s)
KHIDI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Korea, South

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration