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Clinical trial of an anti-tumoural vaccination for patients suffering from stage III/IV malignant melanoma

Submission date	Recruitment status	[ ] Prospectively registered
17/07/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/01/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/01/2009	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
NCT-2007-11-02-1002

Study information

Scientific Title
Phase I trial of RAB38/NY-MEL-1(50-58) peptide combined with Montanide® ISA-51 in HLA-A*0201 patients with stage III/IV malignant melanoma

Acronym
RAB38

Study objectives
In contrast to other solid tumours, immunology plays a major role in malignant melanoma. RAB38 /NY-MEL-1 is a tumour antigen, which is exclusively expressed in melanocytes. Furthermore, antibodies against this polypeptide have exclusively been identified in the sera of patients with malignant melanoma. Therefore, the RAB38/NY-MEL-1 protein is an interesting target for immunisation strategies in these patients. Patients can be included in this study after failure or intolerance of standard chemotherapy. For these patients, other salvage treatments are not yet established and no therapy has been proven to be superior to best supportive care alone. The RAB38/NY-MEL-1 polypeptide has not been used in vaccination protocols before. Other tumour antigens (e.g. NY-ESO 1) have been studied in similar studies, where single patients responded to the vaccination and achieved regression of the tumour manifestations. The tolerability of the vaccination protocols described before was good and severe toxic side effects did not occur in most studies. Within this study, 9 patients with advanced malignant melanoma will be vaccinated with the RAB38/NY-MEL-1(50-58) peptide mixed with Montanide® ISA-51 as an adjuvant.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Ethikkommission der Medizinischen Fakultät Heidelberg) gave approval on the 27th March 2008 (ref: AFmo-278/2007)

Study design
Open-label, single arm, phase I study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

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
Malignant melanoma stage III/IV

Interventions
Patients will receive RAB38/NY-MEL-1 peptide 400 µg mixed with 0.5 mL of Montanide® ISA-51 by intradermal injections, every 3 weeks (weeks 1, 4, 7, 10, 13 and 16) for six doses. Patients without disease progression in the absence of dose-limiting toxicity will receive continued treatment starting 3 weeks after the last injection. Treatment courses will be continued until tumour progression. No dose adjustments during the study are planned.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
RAB38/NY-MEL-1(50-58) peptide, Montanide® ISA-51

Primary outcome measure
1. Toxicities and adverse events (AE) defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE)
2. RAB38/NY-MEL-1 specific cellular and humoral immune responses (CD8 T cell responses, serum antibody responses)

Measured at baseline, week 1, 4, 7, 10, 13, 16 and 19.

Secondary outcome measures
Tumour response will be assessed according to the Response Evaluation Criteria in Solid Tumors (RECIST), measured at week 19.

Overall study start date
01/07/2008

Completion date
30/06/2009

Eligibility

Key inclusion criteria
1. Histologically confirmed metastatic, measurable malignant melanoma stage III/IV who have declined, failed or completed standard therapy
2. Tumour expression of RAB38/NY-MEL-1 by reverse transcriptase-polymerase chain reaction (RT-PCR) analysis
3. HLA-A2 positive
4. Expected survival of at least six months
5. Karnofsky performance scale greater than or equal to 60%
6. Full recovery from surgery
7. Within the last 2 weeks prior to study day 1 the following laboratory parameters, which should be within the ranges specified:

7.1. Absolute neutrophil count (ANC) greater than or equal to 1000/mm^3
7.2. Platelets greater than or equal to 80.000/mm^3
7.3. Creatinine less than or equal to 1.5 mg/L
7.4. Alanine aminotransferase (ALT), aspartate aminotransferase (AST) and total bilirubin all less than 2.5 x upper limit of normal (ULN)
8. Age greater than or equal to 18 years
9. Able and willing to give valid written inform consent
10. Both genders will be included

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
9 patients

Key exclusion criteria
1. Clinically significant heart disease (New York Heart Association [NYHA] class III or IV)
2. Other serious illnesses, e.g., serious infections requiring antibiotics or bleeding disorders
3. Patients with serious intercurrent illness, requiring hospitalisation
4. Patients taking immunosuppressive drugs such as systemic corticosteroids. Topical or inhalational steroids are permitted.
5. Known human immunodeficiency virus (HIV) positivity
6. Other active malignancy within 1 year prior to entry into the study, except for treated non-melanoma skin cancer and cervical carcinoma in situ
7. Mental impairment that may compromise the ability to give informed consent and comply with the requirements of the study
8. Lack of availability for immunological and clinical follow-up assessments
9. Participation in chemotherapy, radiation therapy, or any other clinical trial involving another investigational agent within 4 weeks prior to enrolment
10. Pregnancy or breastfeeding
11. Women of childbearing potential: refusal or inability to use effective means of contraception
12. History of severe allergic reactions to vaccines or unknown allergens

Date of first enrolment
01/07/2008

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Germany

Study participating centre
Medical Oncology
Heidelberg
Germany
69120

Sponsor information

Organisation
University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

Sponsor details
c/o Mrs. Irmtraut Guerkan
Im Neuenheimer Feld 672
Heidelberg
Germany
69120

Sponsor type
Hospital/treatment centre

Website
http://www.klinikum.uni-heidelberg.de/

ROR
https://ror.org/013czdx64

Funder(s)

Funder type
Research organisation

Funder Name
National Center for Tumor Diseases (Germany)

Funder Name
Ludwig Institute for Cancer Research (LICR) (USA)

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