ISRCTN66517336 https://doi.org/10.1186/ISRCTN66517336

Dendritic cell-based immunotherapy in mesothelioma

Submission date 08/03/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/03/2006	**Overall study status** Completed	
Last Edited 11/04/2019	**Condition category** Cancer	

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
NCT00280982

Secondary identifying numbers
NTR600; MEC-2005-269

Study information

Scientific Title
-

Acronym
DC-immunotherapy

Study objectives
Based on studies in other types of cancer in humans where beneficial effects were obtained, and based on our pre-clinical data in a mouse model for malignant mesothelioma (MM), it now seems feasible and warranted to introduce dendritic cell (DC)-immunotherapy for human mesothelioma. It can be expected that using the proper procedure in mesothelioma patients, a beneficial effect of immunotherapy can be obtained without major side effects. The objectives of this phase I study are:
1. To define the safety and toxicity of tumor lysate-pulsed DCs injected in patients with mesothelioma
2. To determine if vaccination with tumor lysate-pulsed DCs results in a detectable immune response by skin delayed type hypersensitivity (DTH) reactions on mesothelioma crude antigen and KLH and by in vitro laboratory analysis
3. To observe and document anti-cancer activity by clinical evaluation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Non-randomised open label uncontrolled single group assignment phase I efficacy study

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Malignant mesothelioma

Interventions

Formulation: autologous monocyte-derived dendritic cells (DCs) pulsed with autologous tumor lysate
Dose: >5 x 10^6 DCs
Route of administration: 1/3 intravenously and 2/3 intradermally
Number of doses: 3
Schedule of doses: every 2 weeks

Intervention Type
Other

Phase
Phase I

Primary outcome measure
1. Safety
2. Tolerability

Secondary outcome measures
1. Anti-tumor responses in vitro and in vivo
2. Clinical response evaluation

Overall study start date
01/01/2006

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Patients with clinically and histologically or cytologically confirmed newly diagnosed mesothelioma, that can be measured in two dimensions by a radiologic imaging study
2. Patients must be at least 18 years old and must be able to give written informed consent
3. Patients must be ambulatory (Karnofsky scale ≥70, or World Health Organisation-Eastern Cooperative Oncology Group [WHO-ECOG] performance status 0,1, or 2) and in stable medical condition. The expected survival must be at least 4 months.
4. Patients must have normal organ function and adequate bone marrow reserve: absolute neutrophil count >1.5 x 10^9/l, platelet count >100 x 10^9/l, and Hb >6.0 mmol/l
5. Positive DTH skin test (induration >2 mm after 48 hours) against at least one positive control antigen of MULTITEST CMI (Pasteur merieux)
6. Stable disease or response after chemotherapy
7. Availability of sufficient tumor material of the patient
8. Ability to return to the Erasmus MC for adequate follow-up as required by this protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Conditions that make the patient unfit for chemotherapy or progressive disease after 4 cycles of chemotherapy
2. Pleurodesis at the affected side before the pleural fluid is obtained
3. Medical or psychological impediment to probable compliance with the protocol
4. Patients on steroid (or other immunosuppressive agents) are excluded on the basis of potential immune suppression. Patients must have had 6 weeks of discontinuation and must stop any such treatment during the time of the study
5. No prior malignancy is allowed except for adequately treated basal cell or squamous cell skin cancer, superficial or in-situ cancer of the bladder or other cancer for which the patient has been disease-free for five years
6. Serious concomitant disease, active infections. Patients with a history of autoimmune disease or organ allografts, or with active acute or chronic infection, including human immunodeficiency virus (HIV) (as determined by enzyme-linked immunosorbent assay [ELISA] and confirmed by Western Blot) and viral hepatitis (as determined by HBsAg and Hepatitis C serology).
7. Patients with serious intercurrent chronic or acute illness such as pulmonary (asthma or chronic obstructive pulmonary disease [COPD]) or cardiac (New York Heart Association [NYHA] class III or IV) or hepatic disease or other illness considered by the study coordinators to constitute an unwarranted high risk for investigational DC treatment
8. Patients with a known allergy to shell fish (contains keyhole limpet hemocyanin [KLH])
9. Pregnant or lactating women
10. Patients with inadequate peripheral vein access to perform leukapheresis
11. Concomitant participation in another clinical trial
12. An organic brain syndrome or other significant psychiatric abnormality which would comprise the ability to give informed consent, and preclude participation in the full protocol and follow-up
13. Absence of assurance of compliance with the protocol. Lack of availability for follow-up assessment.

Date of first enrolment
01/01/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Netherlands

Study participating centre

Erasmus Medical Center
Rotterdam
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3015 GE

Sponsor information

Organisation
Erasmus Medical Center, Department of Pulmonary Medicine (The Netherlands)

Sponsor details
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Sponsor type
Not defined

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Charity

Funder Name
Mesothelioma Applied Research Foundation (MARF) (USA)

Alternative Name(s)
Meso Foundation, Mesothelioma Applied Research Foundation, Inc., The Mesothelioma Applied Research Foundation, Inc., THE MESO FOUNDATION, The Mesothelioma Applied Research Foundation, MARF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
Asbestos Cancer Foundation (Stichting Asbestkanker) (Netherlands)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/05/2005	14/02/2019	Yes	No
Results article	results	15/06/2010	14/02/2019	Yes	No