

Dendritic cell-based immunotherapy in mesothelioma

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J. Hegmans

Contact details
Erasmus Medical Center
Department of Pulmonary Medicine
Dr. Molewaterplein 50
Rotterdam
Netherlands
3015 GE
+31 (0)10 4087703
j.hegmans@erasmusmc.nl

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00280982

Protocol serial number
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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malignant mesothelioma

Interventions

Formulation: autologous monocyte-derived dendritic cells (DCs) pulsed with autologous tumor lysate

Dose: $>5 \times 10^6$ 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(s)

1. Safety
2. Tolerability

Key secondary outcome(s)

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

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 $> 1.5 \times 10^9/l$, platelet count $> 100 \times 10^9/l$, 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Netherlands

3015 GE

Sponsor information

Organisation

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

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

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