

Autologous Dendritic Cell Vaccines in Lung Cancer

Submission date 11/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/02/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/01/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CAAE: 0245.0.146.000-05

Study information

Scientific Title
Mature Autologous Dendritic Cell Vaccines in Advanced Non-Small Cell Lung Cancer

Study objectives

To evaluate the feasibility, safety and immunologic responses in use in mature, antigen-pulsed autologous dendritic cell (DC) vaccine in non-small cell lung cancer (NSCLC) patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Human Research Ethics Committee from State University of Campinas, 27th September 2005 (ref: 452/2005)

Study design

Prospective non-randomised

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Non-Small Lung Cancer

Interventions

1. All selected patients received conventional treatment (chemotherapy with or without radiotherapy).
2. The chemotherapy protocols included paclitaxel 175 mg/m² and cisplatinum 70 mg/m² on day 1. These cycles were then repeated four times every 21 days.
3. After the fourth chemotherapy cycle, the patients were submitted to
 - 3.1. computed tomography (CT) scan of thorax, abdomen and brain to evaluate the tumor response
 - 3.2. Leukapheresis
4. Immunization Protocol: a prime vaccine and a single boost were given fifteen days apart. For each dose of vaccine, two aliquots were prepared in separate syringes with saline solution. First, a dose was subcutaneously administered in the arm and after 1 hour the second dose was given intravenously in the other arm. After the second dose, the patient remained under observation for 1 hour for evaluation of immediate unexpected adverse events.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dendritic Cell Vaccines

Primary outcome(s)

1. Measurable immunologic response: The cellular composition of the immune system, before and after vaccination with the dendritic cells, was assessed from peripheral blood samples using

flow cytometry. The day of immunisation was considered as Day 0. The peripheral blood samples were collected one week before vaccination (Day -7), two weeks after the first dose of vaccine (Day 14), two weeks after the second dose of vaccine (Day 28) and one month (Day 43) after the end of the vaccination protocol. The lymphoproliferation test was used to assess the ability of dendritic cells to stimulate specific lymphocytes in vivo.

2. Safety was evaluated by the clinical and laboratorial evolution according Cancer Therapy Evaluation Program (CTEP) and Common Terminology Criteria for Adverse Events (CTCAEv3)

Key secondary outcome(s)

Therapeutic effects of immunotherapy: tumor response to the vaccine was evaluated by RECISTs criteria

Completion date

30/04/2009

Eligibility

Key inclusion criteria

1. Histopathologically confirmed diagnosis of advanced NSCLC (stage IIIB-IV)
2. Age less than or equal to 70 years
3. Performance status less than or equal to 2
4. No prior chemotherapy, surgery, or radiotherapy
5. No central nervous system metastases
6. At least one measurable lesion according to the Response Evaluation Criteria in Solid Tumours (RECIST) criteria
7. No associated acute disease
8. HLA-A2 phenotype
9. Expression of Wilms Tumor Protein (WT1), Human Epidermal Growth Factor Receptor 2 (HER-2), Carcinoembryonic Antigen (CEA) or Melanoma Antigen 1 (MAGE1) proteins at the tumor site (tissue)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

Progressive disease after conventional treatment

Date of first enrolment

01/10/2005

Date of final enrolment

30/04/2009

Locations

Countries of recruitment

Brazil

Study participating centre

Clinical Pulmonary Service, Department of Internal Medicine, Faculty of Medical Sciences, State University of Campinas.

Campinas

Brazil

13083-970

Sponsor information

Organisation

National Council of Scientific and Technological Development (CNPq) (Brazil)

ROR

<https://ror.org/03swz6y49>

Funder(s)

Funder type

Government

Funder Name

National Council of Scientific and Technological Development (Conselho Nacional de Desenvolvimento Científico e Tecnológico [CNPq]) (Brazil)

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	17/06/2011		Yes	No