

# Autologous Dendritic Cell Vaccines in Lung Cancer

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

**Primary study design**

Interventional

**Study design**

Prospective non-randomised

**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/m<sup>2</sup> and cisplatinum 70 mg/m<sup>2</sup> 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?
<a href="#">Results article</a>	results	17/06/2011		Yes	No