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Autologous Dendritic Cell Vaccines in Lung Cancer

Submission date 11/02/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2011	**Overall study status** Completed	
Last Edited 03/01/2012	**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

Secondary identifying numbers
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

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
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 measure
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)

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

Overall study start date
01/10/2005

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

Age group
Senior

Sex
Both

Target number of participants
5

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.
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Sponsor information

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

Sponsor details
National Council of Scientific and Technological Development (Conselho Nacional de Desenvolvimento Cientifico e Tecnológico [CNPq])
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Sponsor type
Government

Website
http://www.cnpq.br/

ROR
https://ror.org/03swz6y49

Funder(s)

Funder type
Government

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

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	17/06/2011		Yes	No