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Immunotherapy with racotumomab versus support treatment in advanced non-small cell lung cancer patients

Submission date 24/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 03/06/2010	**Overall study status** Completed	
Last Edited 26/06/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gabriela Cinat

Contact details
Instituto "Angel H. Roffo"
Av San Martin 5481
Buenos Aires
Argentina
C1417DTB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AR-RACO-02-08

Study information

Scientific Title
A prospective, randomised, open label phase II study of active specific immunotherapy with racotumomab versus support treatment in patients with advanced non-small cell lung cancer

Study objectives
In patients with stages III/ IV of non-small cell lung cancer (NSCLC) racotumomab versus best support treatment prolongs survival in comparison to support treatment alone.

Please note that a phase III trial with racotumomab is already registered under http://www.controlled-trials.com/ISRCTN47153584.

On 26/06/2014 the anticipated end date was changed from 30/09/2012 to 30/06/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional approvals:
1. Ethics Committee: 02/10/2008
2. Teaching Committee: 08/10/2008
3. Independent Ethics Committee: 22/09/2008
4. MOH approval: 22/06/2009, ref: Disp N°3148/2009

Study design
Prospective randomised open-label phase II study

Primary study design
Interventional

Secondary study design
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 cell lung cancer (advanced)

Interventions

Patients will be randomised to:
1. Best support treatment alone
2. Best support treatment plus racotumomab

All patients will receive best support treatment. In case a second line treatment is indicated, the drug to be used is docetaxel. Patients randomised to racotumomab group will be vaccinated until any causes of permanent discontinuation are met: unacceptable toxicity, intercurrent disease or other reactions that might in the investigator's opinion constitute an exclusion criteria and/or permanently prevent administration for more than 8 weeks, deterioration of the performance status (PS) greater than 3, patient request and/or failure to comply with treatment during 8 or more weeks.

The vaccine is administered intradermically in 4 subdoses at selected sites: deltoid region, anterior forearms, anterior thighs and posterior calf. The first 5 doses are administered at 14 day intervals and the remaining doses at 28 day intervals. If for any reason the vaccine is discontinued the patient will continue with follow up visits (every 2 months) for evaluation of survival just as the patients in the best support treatment arm do. Tumour evaluations will be performed every 8 weeks.

For racotumomab arm only blood sampling for immunological tests will be obtained at baseline for both groups and at month 2, 4, 8 and 12 and every 4 months onwards. For both treatment arms sampling for determination of suppressor cells (T reg) will be performed at baseline, month 2, 4, 8, 12 and every 4 months onwards, at disease progression and upon completion of second line therapy.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Racotumomab

Primary outcome measure
1. Safety: will be evaluated at each study visit according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 3.0 and will include physical examination with vital signs, performance status (ECOG scale), laboratory tests and clinical history. Patients in racotumomab arm attend five biweekly visits (induction period of vaccination), then monthly visits until vaccine is discontinued. After vaccine discontinuation, patients on this arm continue with visits every 2 months. Patients in best supportive care arm: visits every 2 months until end of study.
2. Immunological response to racotumomab: blood sampling for this test will be performed at baseline, month 2, 4, 8 and 12 and thereafter every 4 months until death or patient withdrawal from the study
3. Determination of T reg cells for both arms: blood sampling for this test will be performed at baseline, month 2, 4, 8, 12 and thereafter every 4 months until end of second-line onco-specific therapy

Secondary outcome measures

1. Survival: survival time will be monitored from the date of random assignment to the date of death or last censored observation
2. Progression-free survival: tumour evaluations will be performed from baseline visit and every 2 months and evaluated as per RECIST

Overall study start date
30/09/2009

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. The patient (aged over 21 years, either sex) can comply with the protocol and scheduled appointments and voluntarily sign the informed consent form
2. Diagnosis of NSCLC stages IIIA (surgically unresectable), IIIB or IV, according to the TNM classification version 6a, confirmed by cytology or histology, if possible available for determination of ganglioside expression
3. Patients may enter the study if they have accomplished an objective response (complete response or partial response) or disease stabilisation (by Response Evaluation Criteria In Solid Tumours [RECIST]) after completion of standard onco-specific treatment. In all cases, response should be documented.
3.1. For stage IIIA and IIIB without pleural effusion ('dry IIIB') standard treatment is considered as follows: 2 - 4 cycles of platinum-based chemotherapy and/or radiotherapy with curative intent in accordance with NCCN guidelines
3.2. For stage IIIB with pleural effusion ('wet IIIB') and stage IV standard treatment is considered as follows: 4 - 6 cycles of chemotherapy based on platinum. In case of pleural or pericardial effusion requiring local treatment, it will be provided prior to study entry.
4. Patients with an interval greater than 30 and not more than 90 days between the completion of onco-specific treatment and study entry. Completion of treatment is defined as the last day of administration of chemotherapy or the last day of radiotherapy. Patients should have recovered from any related episode of acute toxicity of degree greater than 1 (except alopecia). Patients who have received a monoclonal antibody (e.g., bevacizumab) should also have discontinued its use for at least 30 days before inclusion.
5. The subject is male or female, aged greater than or equal to 21 years
6. Performance status (Eastern Cooperative Oncology Group [ECOG]) less than or equal to 1
7. Acceptable organ functionality as defined by the following parameters:
7.1. Electrocardiogram (ECG) without significant abnormalities, performed within 14 days prior to admission
7.2. Haemoglobin greater than or equal to 90 g/L
7.3. Total leukocyte count greater than or equal to 3.0 x 10^9/L
7.4. Absolute neutrophil count greater than or equal to 1.5 x 10^9/L
7.5. Total bilirubin less than or equal to 1.5 times upper limit of normal or twice the limit normal than in case liver metastases are present
7.6. Serum glumatate serum glutamic oxaloacetic transaminase (SGOT) and serum glutamic pyruvic transaminase (SGPT) less than or equal to 2.5 times upper limit of normal (less than or equal to five times the normal maximum in case liver metastases are present)
7.7. Creatinine less than or equal to 2 mg/dL
8. Life expectancy of at least 4 months

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Patient is pregnant or breastfeeding
2. Has received chemotherapy, radiotherapy, immunotherapy or surgery within 30 days prior to inclusion
3. Hypersensitivity to any component of the formulation
4. Patients of childbearing potential of either sex who are not using an adequate method of contraception during treatment to avoid pregnancy (own or of partner). For females: intrauterine devices, hormonal contraceptives, barrier methods or sterilisation. For males: vasectomy or condoms with spermicide.
5. Patients receiving or having received other investigational drugs 30 days prior to study entry
6. History of autoimmune diseases
7. Decompensated chronic diseases
8. Acute allergic disorders or history of severe allergic reactions
9. Known brain metastases uncontrolled with surgery and/or radiation therapy or under current corticosteroid therapy
10. History of inflammatory or demyelinating disease of the central or peripheral nervous system
11. Uncontrolled intercurrent illnesses, including active infection, symptomatic congestive heart failure, unstable angina or cardiac arrhythmia and psychiatric diseases implying patient incompetence
12. Other malignancies, with the exception of basal cell carcinoma, in situ cervical carcinoma, incidental prostate cancer (T1a, Gleason less than or equal to 6, prostate specific antigen [PSA] less than 0.5 ng/ml), tumour or any other tumour adequately treated and with a disease-free period greater than or equal to 5 years
13. Chronic treatment with systemic corticosteroids at doses greater than 0.5 mg/kg/day or a maximum of 40 mg/day of prednisone or equivalent
14. The subject has a history of drug abuse (illicit drugs) or alcohol abuse (defined as regular or periodic ingestion of more than four drinks a day) in the last 2 years
15. Positive serology for hepatitis B, C or known human immunodeficiency virus (HIV) infection
16. Uncontrolled hypercalcaemia greater than or equal to 2.9 mmol/L (or grade greater than 1 according to the Common Toxicity Criteria for Adverse Events [CTCAE] version 3.0)

Date of first enrolment
30/09/2009

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Argentina

Study participating centre
Instituto "Angel H. Roffo"
Buenos Aires
Argentina
C1417DTB

Sponsor information

Organisation
Laboratorio ELEA SACIFyA (Argentina)

Sponsor details
Sanabria 2353
Buenos Aires
Argentina
C1417AZE
+54 (0)11 4379 4300
gomezr@elea.com

Sponsor type
Industry

Website
http://www.elea.com/

ROR
https://ror.org/032wae568

Funder(s)

Funder type
Industry

Funder Name
Laboratorio ELEA SACIFyA (Argentina)

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