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Immunotherapy with racotumomab plus best support treatment in comparison to best support treatment alone in advanced non-small cell lung cancer patients

Submission date
19/10/2009

Recruitment status
No longer recruiting

Registration date
30/11/2009

Overall study status
Completed

Last Edited
11/04/2019

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

ClinicalTrials.gov (NCT)
NCT01240447

Protocol serial number
EC-AR-1E10-MAb-301

Study information

Scientific Title
A prospective, randomised, multicentre, open label phase III study of active specific immunotherapy with racotumomab plus best support treatment versus best support treatment in patients with advanced non-small cell lung cancer (NSCLC)

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Brazil: Comitê de Ética em Pesquisa da Faculdade de Medicina do ABC approved on the 24th July 2009 (ref: 168/2009)
2. Argentina: Comité Independiente de Etica para Ensayos en Farmacología Clínica approved on the 29th June 2009
3. Singapore: NHG (National Healthcare Group) Domain Specific Review Board (DSRV) approved on the 30th July 2009 (ref: B/08/530)

Primary study design
Interventional

Study design
Prospective randomised multicentre open label study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Advanced non-small cell lung cancer

Interventions
Patients will be randomised to either:
1. Best support treatment alone, or
2. Best support treatment plus racotumomab

All patients will receive best support treatment, which may include any further oncospecific therapies. 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 permanently prevent administration, deterioration of the PS greater than or equal to 3, indication of the Independent Data Monitoring Committee, use of other experimental therapies and if patient refuses or withdraws from the study or 2 or more consecutive doses of the vaccine are missed.

The vaccine is administered intradermically in 4 sub-doses 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 - 3 months) for evaluation of survival. If the patient was randomised to the best support treatment arm, follow-up visits to evaluate survival will be performed every 3 months after evidence of first progression of disease.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome(s)
1. Overall survival (OS) in the study population as a whole
2. Overall survival (OS) in the subgroup of patients with stages IIIA and dry IIIB

Survival time will be monitored from the date of random assignment to the date of death or last censored observation.

Key secondary outcome(s)
1. Progression free survival (PFS) measured using RECIST; tumour evaluations will be performed from baseline visit and every 2 months
2. Safety (adverse events as per common toxicity criteria [CTC])
3. Correlation of immunological parameters with treatment efficacy

Completion date
01/12/2014

Eligibility

Key inclusion criteria
1. Patients who have voluntarily signed the informed consent
2. Patients with newly diagnosed advanced NSCLC or patients with recurrent NSCLC, at least 1 year after completing curative intent therapy, who present with disease in stages IIIA (non-resectable) or IIIB or IV by TNM classification, confirmed by cytology or histology
3. Patients who have achieved a complete remission (CR) or partial remission (PR) or stable disease (SD) according to Response Evaluation Criteria in Solid Tumours (RECIST) after standard first-line treatment and remain free of progression at the study inclusion time. Standard first-line therapy is defined as:
3.1. For patients with stage IIIA and IIIB, without pleural effusion ('dry IIIB'): 2 to 4 cycles of platinum-based chemotherapy and/or radiotherapy with curative intent as per NCCN guidelines
3.2. For patients with stage IIIB with pleural effusion ('wet IIIB') and stage IV patients: 4 to 6 cycles of platinum-based chemotherapy. In case of pleural or pericardial effusion local therapy, if necessary, will be performed prior to enrolment in the study (catheter setting or draining)
4. Imaging studies documenting the response to first-line therapy must be available for assessment by the investigator
5. Patients with a time lapse of 21 to 56 days between the end of onco-specific treatment and start of vaccination. End of previous onco-specific therapy is defined as 21 days after the last dose of systemic therapy or last administration of radiotherapy. Patients must have recovered from any acute toxicity produced by previous therapy
6. Patients greater than or equal to 18 years of age, either sex
7. Eastern Cooperative Oncology Group (ECOG) performance status (PS) less than or equal to 1
8. Patients with adequate organ function, as defined by the following parameters:

8.1. Electrocardiogram (ECG) without significant anomalies, performed in the 7 days preceding entry
8.2. Haemoglobin greater than or equal to 90 g/L
8.3. Total white blood cell count (WBC) greater than or equal to 3.0 x 10^9/L
8.4. Absolute neutrophil count (ANC) greater than or equal to 1.5 x 10^9/L
8.5. Platelet count greater than 100 x 10^9/L
8.6. Total bilirubin less than or equal to 1.5 fold the maximum normal value at the place of evaluation or 2.5 fold the maximum normal value in case of liver metastasis
8.7. Glutamic-oxaloacetic transaminase/aspartate aminotransferase (GOT/AST), and glutamic-pyruvic transaminase/alanine aminotransferase (GPT/ALT), less than or equal to 2.5 fold the maximum normal value at the place of evaluation (in case of liver metastasis, less than 5 fold the maximum normal value)
8.8. Creatinine less than or equal to 2 mg/dL (less than or equal to 176 µmol/L)
9. Known hepatitis B virus carriers who have liver function tests within the accepted limits are eligible

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnant or breastfeeding patients
2. Patients with known hypersensitivity to any component of the formulation
3. Fertile patients of either sex who do not use adequate contraceptive methods while on treatment
4. Patients whose disease progressed after clinical benefit with first-line onco-specific treatment
5. Patients with recurrent NSCLC, who relapse less than one year after completing curative intent therapy
6. Patients receiving other investigational medication (including investigational immunotherapy for NSCLC) or having received such medication within 30 days before entering the protocol
7. Patients with autoimmune diseases or chronic decompensated diseases
8. Patients with acute allergic disorders or a history of severe allergic reactions
9. Patients with known brain metastases
10. Patients with a history of demyelinating disease or inflammatory disease of the central nervous system or the peripheral nervous system
11. Patients suffering from non-controlled intercurrent diseases, including active infections, symptomatic congestive heart failure, unstable chest angina or heart arrhythmia, as well as mentally incapable patients
12. Patients with other malignant diseases except non- melanoma skin cancer, in situ carcinoma of the cervix, incidental prostate cancer (T1a, Gleason less than or equal to 6, prostate specific

antigen (PSA) less than 0.5 ng/ml) or any other tumour having received adequate treatment and evidencing a disease-free period greater than or equal to 5 years
13. Patients receiving chronic therapy for more than 10 days at doses of prednisone greater than 10 mg/day (or equivalent) at the moment of the inclusion. Inhaled and topical corticosteroids are allowed.
14. Patients with known active hepatitis C or positive tests for human immunodeficiency virus (HIV)

Date of first enrolment
01/12/2009

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
Argentina

Brazil

Cuba

India

Korea, South

Singapore

Taiwan

Uruguay

Study participating centre
Sanabria 2353, 1st floor
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Sponsor information

Organisation
Recombio SL (Spain)

Funder(s)

Funder type
Industry

Funder Name
Recombio SL (Spain)

Funder Name
Laboratorio Elea SACIFyA (Argentina)

Funder Name
Eurofarma Laboratorios Ltda (Brazil)

Funder Name
Innogene Kalbiotech (Singapore)

Funder Name
CIMAB (Cuba)

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	15/07/2014	11/04/2019	Yes	No
Abstract results	results	20/05/2013	11/04/2019	No	No