ForPatients
by Roche

Cáncer de pulmón de células no pequeñasNon Small Cell Lung Carcinoma

A clinical trial to compare atezolizumab given as an injection under the skin, with atezolizumab given as an infusion into the vein, in people with lung cancer who have previously received treatment with chemotherapy

A Study to Investigate Atezolizumab Subcutaneous in Patients With Previously Treated Locally Advanced or Metastatic Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Terminado	23 Countries	NCT03735121 2018-002328-18 BP40657

La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.

Official Title:

Estudio aleatorizado, multicéntrico, fase IB/III para investigar la farmacocinética, eficacia y seguridad de atezolizumab subcutáneo comparado con atezolizumab intravenoso en pacientes con cáncer pulmonar no microcítico localmente avanzado o metastásico previamente tratados

Trial Summary:

La Parte 2 (Fase III, aleatorizada, confirmación de la dosis) apuntará a demostrar la no inferioridad de la exposición al fármaco observada luego del tratamiento con atezolizumab SC a la dosis identificada, comparado con la exposición al fármaco luego del tratamiento con atezolizumab IV. Para más detalle regresar al protocolo

Hoffmann-La Roche Sponsor	**Fase 1/Fase 2** Phase

NCT03735121 2018-002328-18 BP40657
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

How does the BP40657 clinical trial work? This clinical trial is recruiting people who have a type of disease called non-small cell lung cancer (NSCLC). In order to take part, patients must have ‘locally advanced’ (in the lung and lymph nodes) or ‘metastatic’ (has spread to other parts of the body) NSCLC that has previously been treated with chemotherapy.

The purpose of this clinical trial is to compare the effects, good or bad, of two different ways of giving atezolizumab in patients with locally advanced or metastatic NSCLC. If you take part in this clinical trial, you will receive atezolizumab either as an infusion into the vein or as an injection under the skin.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must have been diagnosed with locally advanced or metastatic NSCLC that either did not get better with chemotherapy, or came back (recurred) within 6 months of chemotherapy treatment.

You must not have any uncontrolled brain or spinal cord tumours. If you have previously received particular treatments within a certain amount of time, you may not be able to take part. If you are pregnant or breastfeeding you will not be able to take part.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests very recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you can become pregnant) will need to either not have heterosexual intercourse or use contraception for safety reasons.

What treatment will I be given if I join this clinical trial? This study is being done in two parts. Part 1 is looking at different doses of atezolizumab to find the dose of atezolizumab given as an injection under the skin to be tested in Part 2. In Part 2, the dose found in Part 1 will be used to compare the effects of atezolizumab given as an injection under the skin, with atezolizumab given as an infusion into the vein.

Everyone who joins Part 2 of the clinical trial will be allocated into two groups by chance.

- Group A will receive atezolizumab, given as an infusion into the vein
- Group B will receive atezolizumab, given as an injection under the skin

How often will I be seen in follow-up appointments and for how long?
You will be given the clinical trial treatment atezolizumab as an infusion into the vein or as an injection under the skin, for as long as it can help you. Your treatment visits will also include checks to see how you are responding to the treatment and any side effects that you may be having. You are free to stop this treatment at any time. After being given your last dose of treatment, you will occasionally be contacted by the clinical trial doctor via telephone or asked to return for clinic visits.

What happens if I am unable to take part in this clinical trial?
If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT03735121

Trial-identifier: NCT03735121

Inclusion Criteria:

- Firmar el Formato de Consentimiento Informado -Edad >= 18 años para el momento de firmar el Formato de Consentimiento Informado.
- Habilidad para cumplir con el protocolo del estudio, según el juicio del investigador.
- Enfermedad medible tal como se define en RECIST v1.1 Lesiones previamente irradiadas solo pueden ser consideradas enfermedades medibles si la progresión de la enfermedad ha sido inequívocamente documentada en el sitio desde la radiación y la lesión previamente irradiada no es el único sitio de enfermedad.
- Escala ECOG (Eastern Cooperative Oncology Group) con Rendimiento de 0 o 1.

Exclusion Criteria:

- Metástasis a CNS sintomáticas, no tratadas o progresando activamente
- Compresión medular sin tratamiento definitivo con cirugía y/o radiación, o compresión medular previamente diagnosticada y tratada sin evidencia que ha estado clínicamente estable por
- 2 semanas previas a la inscripción.
- Historia de enfermedad leptomeningea.
- Derrame pleural no controlado, derrame pericárdico, o ascitis que requieran procedimientos de drenaje recurrentemente (una vez al més o más frecuentemente). Pacientes con catéter permanente (e.g., PleurX) están permitidos.

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