Clinical Trial: Neoadjuvant Immunotherapy in Advanced NSCLC

An informed consent form for participants in Power Clinical Trials
Clinical Trial Neoadjuvant Immunotherapy in Advanced NSCLC

Date: November 7, 2021

Clinical Trial Overview

This document is formally inviting you to participate in a medical research study (clinical trial) aimed at evaluating the efficacy of neoadjuvant immunotherapy in advanced non small cell lung cancer. A clinical trial is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a medical study is different from being a patient. This document provides a written summary of the discussion you had in person with our recruitment coordinators and site staff. It's also designed to be a helpful reference for you as a participant, as you continue through the clinical trial process.

Important notes about medical studies

1. Participation is entirely voluntary and you can withdraw at any time. This is not uncommon.
2. All medical studies have inherent risks and benefits. If you have questions about the alternative options, expected side effects associated with neoadjuvant immunotherapy, or potential efficacy, please let us know.
3. It's crucial that, at any point throughout this process if you do not understand what our team is communicating, you raise your hand and let us know.

This medical research has approval from our Institutional Review Board (IRB). These committees, sometimes referred to as ethics committees in other countries, formally review research proposals in order to protect the safety and wellbeing of participants, in line with federal human subject regulations and ethical principles.

Why is this lung cancer research being done?

A number of clinical trials have demonstrated the efficacy of immunotherapy as neoadjuvant therapy. This study evaluates whether said neoadjuvant immunotherapy may improve improve progression free survival in Non-Small Cell Lung Cancer (NSCLC). One such example would be to evaluate either single agent or an immunotherapy combination with chemotherapy. Following this, analysis of biomarkers will be conducted to provide personalization in one's regimen.

What risks should I consider when deciding to participate in this clinical trial?

Altering treatment regimens also contains specific risks. In general, adding neoadjuvant immunotherapy may reduce your quality of life in a number of ways. That said, the specific risks here will depend on the specific treatment regimen you receive. For greater details, please discuss with your care team, or refer to any notes they may have provided when this was first discussed.

Breach of confidentiality is another risk to individuals. Breach of confidentiality could entail

divulging that individuals contacted staff to be screened and completed informed consent forms. The risk of divulging this confidential information is minimal and the potential for identity theft is limited by the way this data will be handled, given the encryption, password protection, and secure, locked office where the Call Log, electronic copies of informed consent forms and deidentified data will be stored and analyzed. There is no possibility of conducting this investigation without the data being used.

What benefits should I consider when deciding to participate in this clinical trial?

The learnings generated by this medical research may help improve outcomes for other patients with non-small cell lung cancer that has entered and advanced stage.

How does this trial compare to other trials for advanced non-small cell lung cancer?

Our staff does not have intimate knowledge of all the available lung cancer clinical trials. However, if you're curious to learn more, feel free to browse lung cancer trials on clinicaltrials.gov, or explore other lung cancer clinical trials on Power's participant reference site.

What is required of me as a patient with advanced NSCLC?

The specific logistics associated with treatment and administration of your neoadjuvant immunotherapy will vary based on your biology, as this trial tailors study protocols based on biomarkers. Our hope is that by tailoring treatment to your specific genes and risk factors, we'll be able to offer a more-effective set of immunotherapy.

To learn more, please talk to your care team about the specifics here.

Have other relevant studies on neoadjuvant immunotherapy been completed?

Yes, a number have been completed prior. Feel free to review them yourself at the link below. Or, if you have specific questions, we would be happy to answer them.

Jiang L, Huang J, Jiang S, Rong W, Shen Y, Li C, Tian Y, Ning J, Chen X, Yang Y, Ding Z, Li Z, Luo Q. The surgical perspective in neoadjuvant immunotherapy for resectable non-small cell lung cancer. Cancer Immunol Immunother. 2021 Aug;70(8):2313-2321. doi: 10.1007/s00262-021-02847-1. Epub 2021 Jan 29. PubMed ID: 33512555

Gutierrez-Sainz L, Cruz-Castellanos P, Higuera O, de Castro-Carpeño J. Neoadjuvant Chemoimmunotherapy in Patients with Resectable Non-small Cell Lung Cancer. Curr Treat Options Oncol. 2021 Aug 23;22(10):91. doi: 10.1007/s11864-021-00885-6. Review. PubMed ID: 34424417

Participant Statement

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____
Participant Signature

_____
Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of Person Conducting Informed Consent Discussion

_____
Person Conducting Informed Consent Discussion Signature

_____
Date