A Phase Ib Study of Pre-Operative Pembrolizumab + Chemoradiation in Patients With Locally Advanced Esophageal Squamous Cell Carcinoma

Department of Thoracic Surgery

Ruijin Hospital Shanghai JiaoTong University School of Medicine

Registration Number: NCT03792347 (www.clinicaltrials.gov)

Date: April 08, 2019

Informed Consent Form

Introduction

We sincerely invite you to participate in a prospective, single-center clinical trial, which was initiated by Prof. Hecheng Li and named "Preoperative Anti-PD-1 Antibody Combined with Chemoradiotherapy for Locally Advanced Squamous Cell Carcinoma of Esophagus (PALACE)".

It is essential to understand the purpose and content of the study before you decide to participate. Please read this introduction carefully and discuss it with your doctor, family and friends. If anything is unclear, or if you want to know more, please ask your doctor or contact the person listed after the introduction.

What is the purpose of the research?

Chemoradiotherapy followed by surgery is the recommended treatment for locally advanced esophageal squamous cell carcinoma (ESCC). Pembrolizumab is an immune checkpoint inhibitor, which has been considered to be safe and effective for patients with advanced esophageal cancer. However, the effectiveness and safety of pembrolizumab in patients with locally advanced ESCC hasn’t been verified. This study was designed to investigate the safety and feasibility of preoperative pembrolizumab combined with chemoradiotherapy for patients with locally advanced ESCC.

Why were you selected?

We invite you to participate in the study, because you have been diagnosed a locally advanced ESCC. Chemoradiotherapy followed by surgery is the optimal treatment plan. The combination of pembrolizumab and chemoradiotherapy before surgery is expected to improve the therapeutic effect with acceptable safety.

Is this research risky?

If you agree to participate in the study, we need to collect your tumor tissue and blood specimen. Blood specimen will be drawn during each routine blood test, and tumor

tissue will be obtained during surgery. These procedures will not make extra harm to your body. Chemoradiotherapy and surgery are routine treatment care, which has its potential risk and adverse events.

Pembrolizumab may potentially cause several side effects including:

1. Immune-mediated pneumonitis;
2. Immune-mediated colitis;
3. Immune-mediated hepatitis;
4. Immune-mediated endocrinopathies;
5. Immune-mediated nephritis and renal dysfunction;
6. Immune-mediated skin adverse reactions;
7. Immune-mediated encephalitis;
8. Embryo-fetal toxicity.

Need to pay?

No extra fee will be needed for participating in the study. You will not receive any compensation for participating in this research. Chemoradiotherapy and surgery can be covered by social medical insurance in China, while, pembrolizumab isn't covered. Your treatment schedule will be properly arranged and followed by a designated doctor.

Is my information confidential?

All information about you is kept strictly confidential during the research process. Only relevant personnel can view your medical records so that they can check the accuracy of the information collected and ensure that the research is conducted normally.

Any information transmitted electronically will be renamed to ensure the confidentiality of the information. The information on all computers will be protected with a password.

The results of the study may be reported at medical conferences and published in scientific journals. However, any information that identifies you personally will not be used.

Do I have to participate?

Participation in the study is entirely voluntary, not forced to participate. If you are participating in a study, you can opt out at any time without any reason. No matter what your decision is, it will not affect your normal treatment or your relationship with your healthcare provider.

If you decide to participate, we will ask you to sign an informed consent form. You will keep a copy of this consent form.

Who conducts this trial?

This study is performed and completed by the Department of Thoracic Surgery, and the Department of Radiotherapy, Ruijin Hospital, Shanghai JiaoTong University School of Medicine.

Who should I contact if I need more information?

After reading this introduction and discussing it with your doctor, if you have additional questions or concerns, please contact the following person:

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Who approved the study?

The study protocol and all amendments were reviewed and approved by the institutional

review board of Ruijin Hospital, Shanghai JiaoTong University School of Medicine (approval No. 2018-180).

I hereby agree to participate in the study.

Name:_____

Signature:_____ Date:_____

Witness Name:_____

Signature:_____ Date:_____