Official title:

Prospective, Multicenter, Non Randomized, Single Arm Study to Evaluate Safety of Transarterial Chemoembolization (TACE) With Doxorubicin Eluting 100 µ Microspheres in Patients With Non Resectable Hepatocellular Carcinoma

ClinicalTrials.gov ID: NCT02670122

Document date: March 2015

TITLE OF THE STUDY:

"Multicenter, observational, prospective, study to assess the security of transarterial chemioembolisation (TACE) with calibrated microspheres and liberating microspheres of 100 microns in the treatment of hepatocellular carcinoma

Study Code FJD-TAN-2014-01

Vascular and Interventional Radiology Service

Ramón y Cajal University Hospital
PI: José Urbano

Introduction

We address you to inform you about a research study in which you are invited to participate. The study has been approved by the corresponding Clinical Research Ethics Committee, in accordance with current legislation, and conforms to the standards of Good Clinical Practice in accordance with the latest update of the Declaration of Helsinki (64th General Assembly, Fortaleza, Brazil , October 2013).

You currently have hepatocellular carcinoma in our center for which the administration of a treatment called "Transarterial Chemoembolisation" (known by the acronym TACE) is indicated. The research study in which it is proposed to participate is entitled "Multicenter, observational, prospective study to evaluate the safety of transarterial chemoembolisation (TACE) with calibrated and doxorubicin-releasing microspheres of 100 microns in the treatment of carcinoma hepatocellular ".

To decide your participation in it, you must understand the purpose of the study. The information you need is found in this Information Sheet provided to you to read carefully. If after reading and clarifying your doubts with the research staff you wish to participate, you will be asked to sign the Informed Consent and a copy of it will be provided.

VOLUNTARY PARTICIPATION

You should know that your participation is voluntary and that you may decide not to participate or change your decision and withdraw your consent at any time, without thereby altering your relationship with your doctor or causing any damage to your treatment.

DESCRIPTION AND OBJECTIVES OF THE STUDY

Transarterial Chemoembolization (TACE) is one of the treatment options that patients who have a non-operable hepatocellular carcinoma have, as is the case. The way to currently administer this treatment is by injecting an anticancer drug (a chemotherapy) into the tumor. This medicine is contained in "microspheres" whose objective is to achieve a greater and more localized effect on the tumor, while reducing the possibility of side effects on the rest of the body. There are different sizes of these microspheres that are used depending on the individual characteristics of each tumor and patient. In your case, the criteria of the doctor who will perform the QETA is that you need treatment with microspheres of 100 microns.

It is important that you understand that in your current situation the administration of TACE with 100 micron microspheres is indicated, so if you agree you will receive this treatment regardless of whether you want to participate or not. This study is aimed at assessing safety (percentage of adverse effects) and efficacy (treatment successes) of this technique, since until now data published in this regard in the scientific literature are scarce.

Your doctor will provide more detailed information about the QUETA procedure and its potential benefits and risks in a separate document specific to it.

In case you have decided to give your consent to participate in the study, information about your medical history, your illness and the treatments you have received or are receiving will be collected. It will be checked if it meets the study selection criteria, and if so, the treatment period will begin according to the usual clinical practice of the center. The treatment received, the complications that may appear and the evolution of the disease will be recorded in detail.

- After the administration of the first treatment session, the following evaluations will be carried out, which are part of the usual clinical practice and would be done the same even if you did not participate in the study:

Clinical and laboratory controls (10-20 days after discharge, every 3 months for the first 6 months and then every 6 months for up to 2 years). In each of these visits:

- Your general health status will be assessed and you will be asked if you have had any medical problems since the last visit.
- A blood test will be done including blood count, coagulation tests, biochemistry and liver function tests. The study can be extended with more complete imaging or analytical tests if the doctor considers it necessary.
- An evaluation of your quality of life will be done through a questionnaire that is commonly used in patients like you (known by the acronym “ECOG”)
- Liver CT or MRI with intravenous contrast every 3 months the first 6 months and then twice a year.

Because of your participation in the study you will not have to undergo any test other than those performed routinely for the control and monitoring of your disease.

During the treatment, if you do not improve sufficiently or get worse, you will be treated by your doctor as usual, who will take the measures you deem appropriate, just as you would if you were not participating in the study.

This study is going to be carried out in 10 University Hospitals in Spain and it is planned to include a total of 130 patients like you.

POSSIBLE ADVERSE EVENTS

This is an observational study in which no procedure is going to be performed other than those performed in normal clinical practice in patients like you, so you will not be exposed to any additional risk for your participation in it.

INSURANCE POLICY

This study is carried out under conditions of "usual clinical practice", which means that the procedure to be performed, the TACE with microspheres releasing doxorubicin of 100 microns, is indicated for the treatment of the disease that you suffer and He would be offered the same even if he did not participate in the study. Therefore, it is considered that he is not exposed to a greater risk than he would have if he did not participate, and it is not considered necessary to contract a specific insurance for the study.

However, any new information that appears in the course of the study on this procedure will be communicated to you as soon as possible.

EXPECTED BENEFITS

You may not directly benefit from participation in this study; However, the information obtained in it will serve to better understand the potential risks and benefits of QUETA with doxorubicin-releasing microspheres of 100 microns in patients who, like you, have a hepatocellular carcinoma not susceptible to surgery.

DATA CONFIDENTIALITY

All clinical information obtained regarding your medical history and current illness will be treated confidentially and anonymously at all times, identifying the data by means of a code and not by name or any other identifier that relates to this information. At all times, the regulations on the processing of personal data regulated by Law 15/1999 on the Protection of Personal Data will be respected.

This study is a non-profit project that aims to answer questions that are considered relevant in the future treatment of patients like you. None of the researchers or the center receive any financial reward for their participation in the study.

If you have any questions about the information you just read, ask the doctor who provided this sheet. For any questions or problems related to the study, you can contact the principal investigator at your center, Dr ._____ (Vascular and Interventional Radiology Service) of the Hospital _____, telephone or the study coordinator investigator, Dr. J. Urbano.

WRITTEN INFORMED CONSENT FOR THE PATIENT

"Multicenter, observational, prospective, study to assess the security of transarterial chemioembolization (queta) with calibrated microspheres and liberating microspheres of 100 microns in the treatment of hepatocellular carcinoma

Study Code FJD-TAN-2014-01

Vascular and Interventional Radiology Service

Hospital Name:

Investigator Name:

Me (Name and surname)

.....

- I have read the information sheet given to me.
- I have been able to ask questions about the study.
- I have received enough information about the study.
- I have spoken with (Name and surname of the researcher)

……..

I understand that my participation is voluntary.

I understand that I can withdraw from the study:
- Whenever you want.
- Without having to explain.
- Without this having an impact on my medical care.

I freely lend my agreement to participate in the study.

In,..... ..... of .... 201.....

Participant's signature ..... Researcher's signature
Date: Date:

WRITTEN INFORMED CONSENT FOR THE FAMILY / LEGAL REPRESENTATIVE

"Multicenter, observational, prospective, study to assess the security of transarterial chemioembolization (queta) with calibrated microspheres and liberating microspheres of 100 microns in the treatment of hepatocellular carcinoma

Study Code FJD-TAN-2014-01

Vascular and Interventional Radiology Service

Hospital Name:

Investigator Name:

Me (Name and surname)

.....

- I have read the information sheet given to me.
- I have been able to ask questions about the study.
- I have received enough information about the study.
- I have spoken with (Name and surname of the researcher)

……..

I understand that my participation is voluntary.

I understand that I can withdraw from the study:
- Whenever you want.
- Without having to explain.
- Without this having an impact on my medical care.

In my presence, all relevant information adapted to their level of understanding has been given to ……. (name of the participant) and agrees to participate. I agree that participates in this study and I give my consent for the access and use of the data in the conditions detailed in the information sheet

I freely lend my agreement to participate in the study.

In,..... ..... of .... 201.....

Participant's signature ..... Researcher's signature
Date: Date: