INFORMATION FOR PATIENTS

European Registry of Clinical, Environmental and Genetic Determinants in Eosinophilic Esophagitis. (EoE CONNECT)

(v.1b – 01/07/16)

Introduction

You or one of your relatives has been diagnosed unequivocally of **Eosinophilic Esophagitis**. This is a particular form of chronic disease with allergic and immunological characteristics affecting the esophagus and causing various symptoms related to the upper gastrointestinal tract. This disease could also alter the quality of life and daily activities of affected patients.

With this document we are requesting your consent to be included in a patient registry. This will allow us to develop epidemiological studies to analyze the effects that previous illnesses, some environmental exposures and genetic factors have in the development of Eosinophilic Esophagitis, in addition we want to identify markers that may help us predict the clinical course or the response to treatment.

This study is being developed in this center, in which you are being treated, and in other hospitals in Europe in a network coordinated by the Spanish Society of Digestive Pathology (SEPD), within the scope of a project supported by the United European Gastroenterology (UEG) and with researchers linked to EUREOS (European Society of Eosinophilic Esophagitis).

Please, read carefully this document and make as many questions as you deem necessary.

Why is important your participation?

Although eosinophilic esophagitis is a disease described just two decades ago, now it is affecting a significant proportion of patients in our area, becoming a common health problem in gastroenterology and allergology consultations.

Our knowledge of this disease is recent, and new studies to properly characterize all aspects of the disease are required. This is especially important because eosinophilic esophagitis is a chronic condition and it may persist, in most cases, over the years. Patient registries and epidemiological studies are among the most potential fruitful research that could be undergone.

What is an epidemiological study?

Epidemiological studies are widely used in medical research and their aims are to find risk factors and protective factors of diseases. In order to find those, we have to obtain information from patients like you.

In other allergic and immunological diseases, we know that there are relationships between some environmental factors and several genes with the onset and/or the clinical course of the disease. Hence the need for new studies to explore eosinophilic esophagitis that is a less explored disease.

The development of this study will be extended to predictive and prognostic markers of disease progression.

Voluntary participation

Your participation in this registry is voluntary.

You are free to withdraw from the registration at any time, and you don't need to specify any reason. Withdrawal will be handled without prejudice on the future of your medical care.

At the time you decide to remove your support, your data will be dissociated irreversibly from your personal information or permanently deleted.

Requested data and other actions

If you give us authorization we will ask you:

- Access to your medical reports. This is required to enable the registry to monitor the clinical course of eosinophilic esophagitis.

- Information about your lifestyle, environmental exposures, history of disease in your family.

- Your permission in order to contact you or your relatives to follow up the evolution of your illness.

Registry data use

The information that you provide specifically for this project will be transferred to a database built *ad hoc* for this study.

Data will be transmitted and stored on a remote server. Only your physician will be responsible for entering your data. He/she can have complete access to all your data (including personal identification data). The use of your data by any doctor or health professional in order to conduct clinical or epidemiological studies will be done after a process of codification, not including personal data.

Only Clinician-researchers that have submitted a project approved by the Research Ethics Committee will have access to clinical data, suitably coded, after a proper approval by the Scientific Committee of the registry, that oversees the quality and good governance of all the records. This Scientific Committee is composed by several doctors and international researchers from different European hospitals.

Benefits

You will not get any direct benefit from your participation in this registry. The use of the clinical data, and eventually if you were in agreement in a future time, any biological samples provided are free (without economic compensation for them). Researchers participating in this project cannot get economic profit with the information held in this registry.

In future studies, the information obtained from this registry could allow a better understanding of the causes of eosinophilic esophagitis and eventually a better treatment of it, that would be a benefit for patients with the disease, as well as for their family and relatives.

Risks

If you participate in this project that aims to study environmental factors and clinical characteristics of the disease, this participation will not involve any risk to you.

Privacy and data protection

The confidentiality of data is ensured in accordance with national and European regulations.

For your information this legislation includes in Spain, the Organic Law of Protection of Personal Data, Law 15/1999, and the Royal Decree 1720/2007 *(ask about your national legislation)*, as well as with European Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

National Legislation on Personal Data Protection:

If new legislative developments are approved, this registry will always be adapted to applicable standards.

The relationship between your participant code and your identity will be properly restricted to the attending physician, and will not be known by anyone else.

The research team will assess the existence of information that may affect your health and they will enable a way to contact you in order to share with you such information. In order to contact you the information contained in your medical records will be used. Please keep your contact information up to date.

It is mandatory that every research study have approval of an Research Ethics Committee. Your personal data will not be disclosed.

You specifically give consent to access your health data file in (Hospital) _____

with the sole purpose of participating in the European Register of Eosinophilic Esophagitis (EoE CONNECT).

Future actions

A patient's registry still becomes more useful when supplemented with the collection of biological samples (saliva and / or blood and / or tissue samples, for example) in what's called a "biobank".

These biological samples are obtained to extract and analyze DNA that allows us to study the presence of genetic variants that affect the course of your disease and response to treatment.

It's possible we will ask you for your DNA samples in a given forthcoming follow-up visit. You will be informed accordingly if the time comes and we will request your consent. Biological samples may include, for instance, blood sample (20 ml) or other sources for DNA (saliva, urine…).

This biological samples will be stored in the biobank of the Hospital and any use will be subject of Research Ethics Committee approval as well as Scientific assessment.

Additionally, we could ask your consent in order to obtain spare tissue cells, coming from a scheduled diagnostic or therapeutic test or procedure, which will also be stored in the biobank for studies of your disease.

We encourage you, when the time comes, to clear any doubts about the benefits, risks and guarantees for such studies. We hope you find these actions of interest. We work to promote activities that aim to facilitate the generation of useful knowledge to better understand this disease and improve the care of patients.

INFORMED CONSENT

European Registry of Clinical, Environmental and Genetic Determinants in Eosinophilic Esophagitis (EoE CONNECT)

.....
(Patient Name and surname in capital letters)

I have read the information sheet given with this consent form.

I have been able to ask all the questions about the study that I've believed necessary

I have received enough information on the study

I have spoken with:

.....
(Researcher name and surname, in capitals)

I accept that:

1. My participation is voluntary

2. My participation does not involve any direct benefit for me

3. My non-acceptance to participate in this registry or withdrawal will not disserve my medical care.

4. The information collected in this record is confidential and it is protected under the law.

☐ I agree to participate in this registry to study environmental factors and disease characteristics of eosinophilic esophagitis.

☐ I would be interested in participating in future studies of genetic factors

Date and **Participant** Signature

(Date and legal representative Signature)

Date and **investigator** Signature

The person that filled in the data in this center (Dr ....) is a doctor of the staff of this Hospital. This doctor can be contacted by calling .....

Physician involved in obtaining this consent .....

You can exercise your rights of access, rectification, cancellation and opposition by contacting the Customer Care Unit located in _____.

REVOCATION OF CONSENT:

I wish to withdraw my consent to this study, so the information I provided cannot be used from this moment on.

I understand that this revocation will not affect the already published results.

I wish to: ☐ irreversibly dissociated my data (anonymize) ☐ erase my data

Revocation Reason (optional):

.....

Date and Participant Signature

(Date and legal representative Signature)