Erdheim-Chester Disease Global Alliance Registry Information

Introduction

The Erdheim-Chester Disease Global Alliance Registry (ECDGAR) is for patients with Erdheim-Chester Disease (ECD). Information from patients with ECD is being collected together because this type of histiocytosis is rare and can cause many different problems, some of the serious.

Many questions about ECD remain unsolved because it is a rare disease and not enough information has been collected to make firm recommendations.

The ECDGAR is being set up with funding from the ECD Global Alliance by a team led by Dr Eli Diamond at Memorial Sloan Kettering Cancer Center in New York, USA. UKHR will submit data for patients with ECD to the registry using a secure online system called REDCap. REDCap is a secure and confidential way to collect information for medical research that is used all over the world (https://www.project-redcap.org/). The database is in English but will be translated into French and Italian.

Aims of the Registry

The aim of the registry is to collect data on patients with ECD. ECD is a relatively rare form of histiocytosis so a global registry will allow more accurate information to be collected more quickly. This will help patients and their medical teams in several ways:

- To find out how common ECD is, whom it affects, and what health problems are caused by ECD
- To collect medical information on the diagnosis and treatment of patients with ECD worldwide
- To collect information directly from patients about the effect of the illness on their lives
- To develop standard treatment protocols and help patients with ECD to access clinical trials of new drugs
- To help doctors advocate for patients with histiocytosis by providing information about how people's lives are affected and what healthcare they require to optimize their quality of life

Data Collected by the Registry

Your year of birth, gender, and ethnicity are required because it is useful to know what group of patients are most often affected. For example ECD is thought to be

most common in older men. The registry will also know you are a UK resident because we are submitting your data. Your participation is anonymous since there is almost no chance that you could be identified from this information. The information will also be treated confidentially and only released to researchers who want to make a contribution to understanding your disease. Although the fact that you have a rare disorder is linked to your identity, your data will only ever be published in a completely anonymous way as part of a cohort or group of patients rather than you as an individual.

The registry will collect as much information as possible about your diagnosis, the course of your illness and the treatment that you have been given. Most of this will be obtained directly from your medical records, pathology reports and x-rays or scans. You may discuss this further with your doctor and let us know if there is anything that you do not wish to be disclosed. The Registry may also invite you to enter information about how your disease affects you through a secure REDCap website. This 'patient-reported' information is a way to tell the Registry anything about your diagnosis, illness or treatment in a completely anonymous and confidential way. The questionnaire will take about 30 minutes.

Medical Images

The ECDGAR has also set up an electronic 'imaging archive', to collect anonymized scans and x-rays, anonymized digitised images of biopsies and anonymized clinical photographs. Your Registry ID Number will be used on all of these the images and you will not be identifiable from them. The electronic images will be supplied to the registry using the same secure system as your data.

Data Security Information

The UK Histiocytosis Registry has a duty and responsibility for safeguarding your information and how it is used. We have reviewed the security of the ECD Global Alliance Registry database and are satisfied that it meets the appropriate standards. The Registry team headed by Dr. Diamond uses the same REDCap Service at their hospital that we use to collect the data in the UK (you can find more information on this at https://www.project-redcap.org/). Details of the security measures are included at the end of this leaflet in a letter from the Team Leader Dr Diamond

Contact Details for the Registry Coordinator

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Dr Eli Diamond
Chief investigator
ECD Global Alliance Registry

To Whom it May Concern

The database platform to be used in this study will be the Research Electronic Data Capture system (REDCap). REDCap is a secure platform within the firewalls of MSKCC and conforms to all regulatory and security requirements in accordance with United States federal, state, local and institutional policies. REDCap allows for electronic consent via the secured platform and is readily used throughout many clinical trials at MSKCC. Additionally, REDCap is user-friendly, secure, and will allow for the distribution of surveys to participants that wish to take part using this secure platform.

Access to this data will be limited to MSKCC study staff and designated staff at Newcastle who require access for coordinating data collection, recruitment, medical record review and/or data entry. External records will be submitted to MSKCC via secured fax or mail, which are standard methods of collecting medical records for standard of care and/or research reasons. Additionally, physical items containing public health information (e.g., scans) will be stored in a locked cabinet within the Department of Neurology with limited access. All physical items from external sources will be de-identified and labeled with a unique code to prevent re-identification. The unique code assigned to each participant will be tracked in REDCap for the sole purpose of linking longitudinal records. No Protected Health Information (PHI) will be transferred from the UKHR to the database (year of birth, gender and ethnicity are not considered to be PHI). Only anonymized data will be exported directly from the database to ensure patient privacy and security. Additionally, designated staff at Newcastle will have access solely to their own dataset as well as de-identified records for those currently enrolled in the registry.

Sincerely,

Eli L. Diamond, MD

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NCI-designated Comprehensive Cancer Center