PIONEER registry

PIONEER Information Sheet

Registry Title: Electroporation Real World Evidence Registry(PIONEER)

Product Name: Electroporation Generator + Electrodes

Study Number: CIP-21-001

Study Version: 2.0

Investigator Name:

Investigator Address:

Sponsor Name and Address: Mirai Medical, 5 Howley Court, Oranmore, Galway, H91 P5PH, Ireland

IRAS Study ID: 292649

PIS Version: 2.0 Date: 29 APRIL 2021

1. Invitation

You are being invited to participate in a research study registry to investigate the effectiveness of treating cancers with a new medical therapy. Before you decide whether or not you should agree to be part of this study, it is important for you to understand why the research is being done and what it will involve, as well as the possible risks, benefits and discomforts. This process is known as Informed Consent.

This Patient Information Leaflet gives detailed information about the study registry that your doctor will discuss with you. Please take time to read the following information carefully and make sure you fully understand it, and discuss it with others if you wish. If there is anything that is not clear or if you would like more information about something mentioned in this leaflet, or have any questions about this research study, please be sure to ask your study doctor or nurse. Take time to decide whether or not you wish to take part.

2. What is the purpose of the PIONEER Registry?

The aim of this study registry is to investigate the short and long term effect of electroporation in combination with chemotherapy (electrochemotherapy) and the short and long term effect of electroporation in combination with calcium (Ca-electroporation) in the management of skin cancers. A study registry is a collection of anonymous information on patients who have a particular disease or condition. It also contains information about treatment and the results of the treatment. The information is stored electronically. When sufficient data are collected in the registry, the research team will communicate the results through publications and reports with a goal of advancing treatment options for cancer patients.

3. Will my taking part in this study be kept confidential?

Yes. In this research study, your study doctor and staff will collect information about you from your medical records. We will only use information that we need for the study registry. No-one will know your name or contact details. Everyone involved in this study registry will keep your data safe and secure. We will also follow all privacy rules. We will make sure no-one can work out who you are from the reports we write. GDPR information below describes how your information will be used, your available choices and who you can

contact if you have a complaint. Additional GDPR information is available in a supplementary patient information leaflet.

4. Why have I been chosen?

You have been invited to participate in this study registry as you have already been treated or are about to be treated with electrochemotherapy or Ca-Electroporation by your doctor.

5. Do I have to take part?

No. Your participation in this study registry is entirely voluntary. It is up to you to decide whether to take part or not. If you do decide to take part, you will be asked to sign the attached consent form and given a copy of this information leaflet to keep. If you decide to take part but later change your mind, you are free to leave the study at any time without giving a reason. This will not affect your future medical care in any way. Your study doctor may withdraw you from the study if he/she feels this is in your best interest or in case of stopping the study early.

6. What will happen to me if I take part?

Information about your condition and treatment will be uploaded to an electronic database. This information will be completely anonymised. That is, there will be no personal information, nor information which can be traced back to you stored in the database. Your doctor may take a photograph of the main lesion for upload to the registry. Your doctor will ensure that the photograph is of your lesion, only and that no identifiable features are included. Your doctor will routinely follow up with you as defined in your care plan.

7. What will I have to do?

You must sign and date this informed consent form before having your anonymised information included in the study registry.

We will collect the following information;

- Diagnosis Information
    - Type of Cancer
    - Size of Main Lesion
    - Location of Main Lesion
    - Previous Treatments – if any.
- Treatment Information
    - Anaesthetic Used
    - Therapeutic Used (Chemotherapy or Calcium)
    - Type of electroporation
    - Your satisfaction with the treatment
    - Regulatory information about the devices used
- Follow-Up

- Your clinical response to the treatment
- Your personal feedback on the treatment

8. What are the possible benefits of taking part?

It is hoped that the treatment you have received or are about to receive will help you. There is no guarantee that your participation in this study registry will help you personally. The potential benefit to storing information in the study registry include the development of new alternatives to existing therapies for existing cancers.

9. What are the side-effects and downside of taking part?

There are no side effects for taking part in this study registry. There are no costs to you personally as this is a clinical research study. Unfortunately there is no payment for taking part in the study. If additional information becomes available about possible risks associated with the procedures involved in this study, this information will be provided to you immediately.

10. Who is organising and funding the research?

Mirai Medical, Ireland will provide the database and technical support to the study.

11. Who has reviewed the study registry?

The registry has been reviewed and given a positive opinion by the Leeds East Research Ethics Committee .

12.What are your choices about how your information is used?

You can stop being part of the study registry at any time, without giving a reason. If you want to exit the registry, you should speak with your doctor and let them know. If you want us to remove the information about you that we already have stored in the database, then you should let your doctor know. This will not jeopardise any treatment that you receive or your relationship with the data collection centre and doctor.

Your doctor will provide the unique ID to the database team to remove all of your records from the database. The audit trail of the deletion of these data will be provided to you by your doctor as a record. A report showing that these data have been successfully deleted may may take up to 15 days. For further information see the GDPR leaflet attached.

13.Who can I contact if I have a complaint?

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer.

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

Informed Consent Signature Page

		Place Initials in Box
1.	I confirm that I have read and understand the Participant Information Sheet (Version 2.0) and Consent Form for the PIONEER Registry (April 29th 2021). I have had the opportunity to ask questions. This information was explained to me and my questions were answered.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3.	I agree with the anonymous collection of all data concerning my course of treatment and to the upload of this data, including photographs of lesions on my body to PIONEER and to its dissemination.	
4.	I understand that sections of any medical notes may be looked at by responsible individuals from the sponsor or from regulatory authorities and all organisations as listed in this Informed Consent Form, where it is relevant to my taking part in research, provided they agree not to disclose my name. I give permission for these individuals to have access to my records.	
5.	I agree that the data collected for the study will be used for the purpose set forth above, including transferring to the sponsor company in anonymised form with respect of the confidentiality of my data, will be processed and analysed as is required by this clinical study and according to the GDPR. This will not waive any rights that I have under local law.	
6.	I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.	
7.	I agree to take part in this study registry	

Informed Consent Form signatures:

_____ _____ _____

Patient (Print Name) Patient Signature Date

_____ _____ _____

Name of Investigator (Print Name & Title) Signature Date

To be signed and dated simultaneously, i.e. same date, by all parties

Distribution: original for study doctor and stored in the patient record, copy to Patient

Revocation of Consent

Registry Title: Electroporation Real World Evidence Registry(PIONEER)

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To be used by patients who wish to withdraw from PIONEER.

Data Collection Centre		
Principal Investigator		
		Place Initials in box
I hereby wish to WITHDRAW my consent to participate in the research study described above and understand that withdrawal will not jeopardise any of my treatment or my relationships with the Data Collection Centre listed above and the Principal Investigator listed above.		
I would like all of my data to be removed from the PIONEER database.	YES / NO	

_____ _____ _____

Patient (Print Name) Patient Signature Date

_____ _____ _____

Name of Investigator (Print Name & Title) Signature Date

To be signed and dated simultaneously, i.e. same date, by all parties

Distribution: original for PI and stored in patient record, copy to Patient

Data Removal Request

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To be used by principal investigators who wish to remove patient data from PIONEER.

Data Collection Centre		
Principal Investigator		
		Place Initials in box
On behalf of patient [INSERT PIONEER UNIQUE ID] I hereby request that all data on the patient be removed from PIONEER. The patient has been informed that this request will not jeopardise any treatment or their relationship with the Data Collection Centre listed above or the Principal Investigator listed above.		

_____ _____ _____

Name of Investigator (Print Name & Title) | Signature | Date

Distribution: original for PI and stored in patient record, copy to PIONEER GSLG.