International Registry for Nanoknife™ prostate cancer treatments

Information About the Registry

Joining the registry

Why are we running a registry?

We are running a registry on Irreversible Electroporation (IRE or Nanoknife™) treatment for prostate cancer to gain a better understanding of the effectiveness the treatment in terms of cancer control, and how good it is in terms to minimising side effects like urinary incontinence and erection problems in the men who are treated. We're keen to do this as Nanoknife™ is a newer treatment and these results are not yet available in the long term (5-10 years). The UK and international guidelines recommend collecting data in this way. All data is kept to the highest security standards (GDPR and HIPA).

Do you have to take part?

It's up to you. We invite you to take part as the registry helps us to fulfil our obligation to NICE (the National Institute for Health and Care Excellence), the UK healthcare guidelines body, but the decision is entirely yours and we will accept it either way. You don't have to tell us why if you don't want to join the registry.

Are the advantages to taking part?

The main goal of the registry is to allow us to report on the effectiveness of Nanoknife™ to the prostate cancer community which we hope will allow more men to access the treatment. Surgeons will also be able to easily monitor how a Nanoknife™ program is going at their hospital.

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We've designed the registry also to improve communication between surgeons and patients. It will provide you with information that we hope will allow you a better understanding of the type of prostate cancer you have and the treatment being offered.

Finally, the registry will also allow you to easily send us information on any problems you may be having with urinary continence, erections or quality of life after the procedure. This feedback is key to a complete understanding of the treatment.

Can you change your mind later?

Absolutely. You're free to withdraw from the registry at any time and you don't have to give a reason. Please contact us by one of the methods at the end of this document.

About Your Data

We collect the minimum personal data such as name, age, and contact details needed to study the Nanoknife™ treatment and get in touch with you. We'll ask you for an email address when we invite you to take part in the registry. The clinical data we collect covers the type of prostate cancer you have, including MRI and biopsy results, as well as details of the Nanoknife™ treatment. This will come from your standard NHS record. We'll continue to collect this sort of data as we follow you up after your cancer treatment. Our goal is to accumulate 10 years of follow up data in total as this period represents the gold standard when analysing a prostate cancer treatment.

What will we do with the data?

The goals of the registry are as follows

1. Collect data about prostate Nanoknife treatments to allow for a better understanding of its effectiveness as a cancer treatment and its ability to keep the side effects low compared with whole prostate treatment (surgery or radiotherapy).

2. Analyse and publish the data in the scientific literature to spread this understanding. All publications and dissemination of results from the registry will be anonymous. You will not be identified personally in any report or publication.
3. Allow individual surgeons to understand their own results and with their institution to deliver the highest quality care.
4. Improve the communication between patient and surgeon over the nature of a prostate cancer and the planned treatment, as well the quality of life of patients after treatment.

How will we protect the data and your identity?

We will hold your data in a secure electronic database within the UK. The electronic storage is compliant with strict standards for both the UK and Europe (GDPR) and the US (HIPA). The company storing the data, Dendrite Clinical Systems, has a long history of providing such services both within the UK and internationally, and adheres to the highest ethical and legal standards.

Any analysed data we use for reporting to the scientific community on the effectiveness of Nanoknife treatments will be anonymised so you and your personal details will not be identifiable. Analysts or researchers working on these reports will only have access to the specific data required for then project they are undertaking.

Who will have access to your data?

Access to the database will be carefully restricted. Those with access will include surgeons and their teams offering Nanoknife treatment as well as researchers attached to those teams. A panel of the surgeons involved as well as appropriate team members will oversee any access requests.

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How will any research projects be approved?

Research projects requiring data from the registry will need to have appropriate approval from their institutions as well as ethics committee approval if appropriate. The core data in the registry is collected as monitoring of an existing NHS treatment rather than as a research project.

How long will we keep your data for?

Prostate cancer is a slow growing disease and one requires long term follow up data to fully understand the effect of a treatment. 10 years of follow up after the treatment is the gold standard for prostate cancer though we may keep your data longer than this as everybody in the registry will need to have been there for 10 years to achieve this threshold.

Can I access my data?

Yes . Most of the data in the registry will have come from your standard medical notes and you have a right to see these anyway. One of the aims of the registry is to improve communication between patient and surgeon and it will generate reports that you should receive by email giving you details of MRI and biopsy findings. Any other information you want will be available on request. For full details on your rights under data protection law please visit our website on https://ire.e-dendrite.com.

How is the Arc registry funded?

The Arc registry has been funded by a generous grant from Angiodynamics Ltd, the company who manufacture the Nanoknife equipment. Both Angiodynamics and the Arc registry team understand the need for objectivity in this sort of project however and

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Angiodynamics have not influenced the design and running of the registry, nor will they have any access to the confidential patient data it stores.

Who is responsible for looking after the data?

The Arc registry team is the data controller as part of UCLH. We are registered with the Information Commissioners Office (UCLH ICO Registration Z8727593)

How can I complain or give feedback?

If you're unhappy about any aspect of the registry, please do get in touch and let us know. You can do so formally or informally using the contact details below. We'd also love to hear from your if you have any suggestions as to how we might improve the registry processes or any other aspect.

Contacts:

Lead urologist for Arc Registry: Alistair Grey

Email contact UCLH: ARCregistry@nhs.net

Thank you