EASi-KIDNEY

Aldosterone Synthase inhibition & Empagliflozin in CKD

Data Protection Information Leaflet

This leaflet explains how data from EASi-KIDNEY participants are processed

Who is responsible for my data?

The University of Oxford and Boehringer Ingelheim are the 'data controller' for all the information and data collected in the EASi-KIDNEY trial. This means that the University of Oxford and Boehringer Ingelheim are responsible for looking after the data collected about you for EASi-KIDNEY and using them properly.

The trial is being designed and conducted using funds from a grant to the University of Oxford from a company called Boehringer Ingelheim. They are the trial's sponsor and their role is explained in more detail on the following pages.

How will data about me be collected if I decide to join the study?

During your participation in the study, you will provide personal data about yourself, such as information on your medical condition and medical history, to the study nurses at your study visits (and relevant blood and urine test results held at your hospital). We will also record and store your contact details, such as your email address, to communicate with you about the EASi-KIDNEY trial and we will ask you if these contact details can be used after the study has ended to ask you for updated information about your health and to invite you to future studies.

In addition, the coordinating centre in Oxford will ask for information about your health from your doctors, registries (such as the UK Renal Registry), NHS England (or other central NHS bodies), and the NHS Diabetic Eye Screening Programme (if you have diabetes). The EASi-KIDNEY team send your name, date of birth, NHS number (or CHI number in Scotland, or H&C number in Northern Ireland) and postcode to NHS England (or another central NHS body) who can link this information to individual participants in the study.

These sources can provide information about people who have died which may mean the study team does not make contact and cause any distress to relatives. Your name, date of birth, NHS number (or CHI number in Scotland or H&C number in Northern Ireland) and postcode will be stored securely by the University of Oxford for the purposes of this linkage. Personal identifiers will NOT be sent to anyone else (including Boehringer Ingelheim, the drug company who make empagliflozin and BI 690517).

At any time, you may decide you are no longer willing to attend the study clinic. In this case, the local study team will ask if they can continue to contact you or a relative by telephone or access your medical records to continue to collect information about your health in relation to the EASi-KIDNEY trial. You may also contact the study team to withdraw permission for the study to get this information about you (see back page for contact details) but we will keep information about you that we have already collected.

How long will my data be kept if I join the study?

The University of Oxford plans to keep the information collected about you (and Boehringer Ingelheim will safely keep a copy of the de-identified database) for at least 25 years after the end of the study and perhaps longer if required by the law or other research needs to undertake the EASi-KIDNEY trial. This is so the results of the trial can be checked by healthcare regulators, such as the Medicines and Healthcare products Regulatory Agency (MHRA), U.S. Food and Drug Administration (U.S. FDA) or European Medicines Agency, if needed.

What are my rights?

There are an increasing number of data protection regulations that we are required to follow. These laws require us to disclose your rights and how we will use your data. Both institutions will use your personal data for research purposes.

The University of Oxford will only use personal data when needed to undertake research that is being carried out in the public interest. This is known under data protection law as our 'legal basis' for processing your personal data (General Data Protection Regulation (GDPR) Article 6(1)(e) and Article 9(2)(j)). This means that when you agree to take part in a research study, we will use your data (including your health data) in the ways needed to conduct and analyse the research study. You can find out more about your data rights under GDPR on the study website **www.easikidney.org**.

Boehringer Ingelheim will use 'legitimate interests' as the 'legal basis' for processing your personal data in order to ensure the high standardsof quality and safety of their medicinal products.

How will the EASi-KIDNEY team keep my data safe during the study?

The University of Oxford is a world-leader in developing systems to ensure that information is stored safely for studies such as EASi-KIDNEY.

We will protect your personal data against unauthorised access, unlawful use, accidental loss, corruption or destruction.

We will use technical measures such as encryption (where the data are scrambled and can only be read by someone who has access to the special code) and password protection to protect your data and the systems they are held in.

To help keep your information confidential, information recorded about you in this study as well as any samples collected are “de-identified”. De-identified means that your health information and blood/urine samples are labelled with unique numbers linked inside a computer and **not** by your name.

We will also use operational measures to protect the data, for example by ensuring that all staff are trained on data security. We keep these security measures under review and refer to University of Oxford security policies to keep up to date with current good practice.

Who is responsible for and has access to my data during the study?

The two parties involved in this trial (the University of Oxford, whose full legal name is “The Chancellor, Masters and Scholars of the University of Oxford”, and Boehringer Ingelheim International GmbH) will be responsible for deciding how any personal data collected during this study are processed and will ensure data protection laws are followed (ie they will be the “data controllers”). Both parties are bound by a duty of confidentiality.

Only staff with appropriate training and permission can access the bespoke computer system used to store your data. Personal data that directly identifies you such as your name, address, or date of birth (so-called personal identifiers) can be accessed by the EASi-KIDNEY doctors and nurses who are running the study at your local hospital. Health regulators (such as the UK MHRA and U.S. FDA) and auditors from

Boehringer Ingelheim could also access these data if they were to ever visit your local hospital to check that the study is being carried out properly. (Such visits may be conducted remotely through an appropriate platform). These people are also all bound by a duty of confidentiality.

During the study, a member of the Oxford University team or other EASi-KIDNEY staff may ask your permission to be present during your clinic appointment to observe a visit. This helps us ensure study procedures are being followed.

Will data about me be shared during the study?

Personally identifiable data about you will only be shared with authorised third parties (see previous section), NHS organisations and national registries so that the health data about you can be provided to the study, healthcare regulators (such as the MHRA or U.S. FDA), and other statutory bodies or Boehringer Ingelheim during an audit or inspection.

The University of Oxford is convinced that access to trial data advances clinical science and medical knowledge and is in the best interest of patients and public health, provided that patient privacy is protected. Therefore, de-personalised data – data which has had identifying information removed – may be shared with healthcare regulators, other credible researchers and Boehringer Ingelheim for the purposes of finding out more about kidney disease. De-personalised data about you will only be shared with legal safeguards to protect the data. De-personalised data may be sent outside the UK and EU. A legal contract will ensure that anyone receiving these data must follow our rules about keeping these data safely. If any

foreign country to which de-identified data is transferred does not have equivalent data protection standards to those required in the UK, appropriate safeguards will be adopted to protect and maintain the confidentiality of your data and blood/urine samples (including using standard data protection clauses adopted by the European Commission, where relevant). If you require any information about these safeguards, you may contact us: data.protection@admin.ox.ac.uk.

De-personalised data has had identifying information removed however it might be possible to re-identify the individual if the data are not adequately protected or if it is combined with different sources.

De-personalised data are a bit like the blurred photograph: if you already knew quite a lot about the individual (for example where the photograph was taken and what they were wearing) it might be possible to identify them, but they are not recognisable just from the photo.

As already explained above, it is really very hard for anyone to re-identify you after de-identification as we use special measures to protect data, but it remains theoretically possible. The “de-identified” data in this study will be used for the following purposes: analysis of the study results, to help learn more about how the study treatment works in the body, to do future research, to write scientific articles on kidney diseases and associated health problems, and to help design and conduct future studies.

Oxford and Boehringer Ingelheim (including Boehringer Ingelheim group of companies) may process and combine data from this study with data from other sources (always using appropriate safeguards) and may carry out these activities alone or in collaboration with public or commercial private partnerships (ie third parties) in the areas of research described above.

What are my data protection rights?

If you stop taking the study pills and do not wish to have further blood samples to be collected at your study clinic, it would be very helpful if we could keep in touch by phone. However, you can also decline to be contacted again. In this case, we would like to continue to follow how you are getting on by contacting your local doctor (eg your GP/primary care physician) or through national registries or other publically available sources of data.

If you decide you do not want any new information about you to be collected and used for the study (known as “withdrawal of consent”), we will ask you or your local clinical team to sign a form and will not collect any further information from you. All information collected, including analysis results from blood and

urine samples that have been already collected, will still be kept and used for the study. Although no further information will be collected from you after withdrawal, the study will use death records which are publically available to help ensure complete information and a reliable result. Such data would still be recorded.

If you have previously given consent for us to use leftover blood and urine samples and related information which had been collected in the study, you may also separately withdraw your permission for this optional part of the study at any point in time, without affecting your participation in the main part of the study. Any samples that you no longer wish for us to store or use will be destroyed.

You have the right to request to know what personal data the University of Oxford and Boehringer Ingelheim hold about you and to have a copy of that data. Your local study nurse could provide this, however, to ensure the study's scientific integrity, you may not be able to review such data until after the study has been completed.

You also have the right to to request to correct wrong or outdated personal data. However, the study site and Boehringer Ingelheim (as the study's sponsor) may be obliged by law to keep your data to ensure consistency and reproducibility of the results and we cannot delete data that has already been used in analyses (note that analyses are run regularly throughout the study).

You also have the right to request to restrict or object to what we do with your data. However, sometimes the data controllers may not be able to (or have grounds not to) follow a request from you, for example, if we consider that deleting your data would seriously harm the research. If you would like to exercise any of these rights, please contact us. The data

protection officer for the University of Oxford can be contacted by email at: **data.protection@admin.ox.ac.uk**.

Complaints

If you wish to raise a complaint about how we have handled your personal data, you can contact our data protection officer at **data.protection@admin.ox.ac.uk**, who will investigate the matter.

You also have the right to complain to the Information Commissioner's Office (ICO) via: **https://ico.org.uk/concerns/handling/**.

Contact information

By telephone:
0808 164 4060 (UK 24-hour freephone number)
+44 1865 743868 (from outside the UK)

By post:
EASi-KIDNEY Central Coordinating Office
Clinical Trial Service Unit and Epidemiological Studies Unit
Oxford Population Health
Richard Doll Building
University of Oxford
Roosevelt Drive
OXFORD
OX3 7LF

By email: cco.easikidney@ndph.ox.ac.uk

Website: www.easikidney.org

Please contact the EASi-KIDNEY office if you would like to receive this document in another format.

IRAS: 1009666

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