EMPA-KIDNEY

The study of heart and kidney protection with empagliflozin

You are invited to join a major new health research study

This study is testing a treatment which may help prevent people with kidney disease from needing dialysis and we need your help

MRC Population Health Research Unit

UNIVERSITY OF OXFORD

EMPA-KIDNEY - Quick Summary

- You are invited to join an important health research study called EMPA-KIDNEY. Its longer name is *The Study of Heart and Kidney Protection with Empagliflozin*
- It is entirely up to you if you take part or not
- EMPA-KIDNEY is testing whether taking a medication called empagliflozin lowers the risk of worsening kidney disease or heart disease in patients with kidney disease
- Empagliflozin was originally developed to treat people with diabetes. In a large clinical trial, empagliflozin reduced the number of deaths from heart disease in people who already had both heart disease and type 2 diabetes
- The same clinical trial suggested that this medication could reduce the development or worsening of kidney disease in these patients
- Because of the way empagliflozin works on the kidney there is good reason to believe it could benefit people whether they have diabetes or not. Scientists based at Oxford University want to find out whether taking an empagliflozin pill once a day prevents worsening of kidney disease or death from heart disease in people with kidney disease
- If you agree to take part, you will be joining about 5,000 other volunteers
- Half of the people will get an empagliflozin pill to take once a day and the other half will get a dummy inactive pill (known as placebo). Which treatment you receive is decided by chance and you will not know which treatment you are given
- Joining the study involves attending 3 clinic appointments in the first 6 months and then an appointment once every 6 months. At each appointment a trained researcher (usually a research nurse) will ask some questions about your health and give you a supply of study pills
- Because kidney disease is identified and tracked by blood and urine tests, at each appointment you will be asked to provide a blood and occasionally a urine sample (even if you stop taking your study pills)
- You are asked to stay in the study for about 3-4 years – it needs to be this long to make sure this study is a definitive test of this pill on kidney disease which often takes several years to progress
- We would like to also use medical and civil registration records (e.g. those maintained by NHS Digital and the UK Renal Registry) to follow your progress
- If you join the study, your GP will be informed and your usual medical care will not be affected by taking part
- The University of Oxford are running the study. Study pills and a grant to run the study have been provided by Boehringer Ingelheim International GmbH (the drug company who make empagliflozin)
- If you'd like to find out more, please read the rest of this leaflet carefully

Kidney disease is common and linked with heart disease

Chronic kidney disease (CKD) is a common condition, affecting about 10%-15% of the population. It is diagnosed and monitored by means of blood and urine tests.

CKD is caused by many different things, including increasing age. Diabetes, high blood pressure, inflammation in the kidney and inherited diseases are the most common in the UK.

It is known that people with kidney disease are both at risk of their kidney problem worsening and developing heart problems.

New treatments for kidney disease and heart disease are needed

Twenty years ago, a group of medications which block a biological system, called the *renin-angiotensin system* (RAS), were shown to protect the kidney and the heart. Because of these clinical trials, these medications are now widely used (and you may be taking one: their names end in '–pril' or '–sartan'). These simple treatments have meant some people have not needed to start dialysis and have saved lives.

However, despite taking RAS blockers, many people with kidney problems continue to develop worsening of their kidney disease and/or heart problems. Scientists are searching for new treatments to reduce the remaining risk of kidney and heart problems in people with kidney disease.

There is now a new medication called empagliflozin which was originally developed to treat high blood sugar in people with diabetes, but has recently been shown to have beneficial effects on both the heart and kidney.

What is the treatment being tested?

Empagliflozin causes blood sugar (equivalent to 10 teaspoons a day) to pass into the urine. It likely also increases the amount of salt (sodium) passing into the urine. This results in a modest fall in body weight and blood pressure.

Importantly, a large clinical trial has shown that empagliflozin reduces the number of deaths from heart disease in people who already have both heart disease and type 2 diabetes. Because of these results, empagliflozin is used in selected patients with diabetes around the world.

The same study suggested empagliflozin might reduce kidney problems. From the way we think the pills work, there is good reason to believe this new medication could benefit people who have kidney disease, whether they have diabetes or not.

What is the key question the study will answer?

EMPA-KIDNEY is a research study coordinated by the University of Oxford.

The scientists in Oxford want to find out whether taking a single pill of empagliflozin every day prevents worsening of kidney disease or deaths from heart disease in people who have kidney disease.

Why me?

Your doctor has reviewed existing blood and urine test results which show some evidence that you have protein in your urine or reduced

kidney function in the past. You are probably already aware of this, but you may not be, and it is also possible that the protein in your urine or reduced kidney function is no longer present.

You have therefore been invited to a study appointment to test your blood and urine again, and to discuss taking part in the study.

The scientists need a range of people to join the study, including those with only early signs of kidney disease risk as well as people who have already seen a kidney doctor.

You do not have to have diabetes to take part, in fact the study needs lots of people with and without diabetes to join.

Do I need to take part?

No, you do not have to take part in this study. It is entirely your decision. It is important to be aware that if you join this study, it will not affect any decisions about other medical treatment you might need or be receiving from your own doctors.

If you do decide to come to the first study appointment you will be given an opportunity to ask questions about the study. Once we have rechecked your blood and urine tests, we will also check with the hospital doctor leading the trial in your hospital that they think you are appropriate to join the study and we will also tell your GP that you wish to take part.

By joining this study, you will become part of our efforts to save the lives of people with kidney problems and hopefully reduce the need for kidney dialysis in years to come.

Travel expenses

The study can pay you back for all reasonable costs for travelling to your study appointments (e.g. car parking and petrol or other transport costs). Please make sure you ask at the clinic.

Otherwise taking part in the study is voluntary and you will not receive payment for your participation (i.e. you are donating your time, information about your health, and samples of your blood and urine).

Who decides what treatment I get?

Half the people taking part in this study will get the empagliflozin pill and half will get the dummy inactive pill (known as placebo). Which treatment you get will be decided by the computer by chance (like tossing a coin). This is called randomization.

You, and your doctors, will not know which treatment you are given and the study staff will not know either. This ensures the study gives results which are reliable and trustworthy.

Are there any alternative treatments?

During the study you should continue to take any other treatments you may have been given to treat your kidneys. Indeed, your local doctors will be asked to ensure they continue to treat your other medical problems according to guidance produced by experts at a local, national or international level.

Note that if you are already taking empagliflozin (or any medication with the name ending in "–gliflozin"), you will not be able to join this study.

What will I have to do?

For EMPA-KIDNEY to be able to give reliable results, it is important that people stay in the study and take their study pill every day for about 3-4 years, wherever possible.

The study needs to be this long so it is a definitive test of the effects of the pills on kidney disease which can take years to progress. The results of the study could have a major impact on how kidney patients around the world are treated.

By joining the study, we are asking you to attend the study clinic 3 times in the first 6 months, and then attend every 6 months after that.

At each study appointment, a trained researcher (usually a nurse) will ask you about your health and give you a new supply of study pills. You will then have a blood sample taken to monitor your kidneys and other effects of the study pills.

At a small number of visits, we will also ask you to provide a urine sample.

With your permission, we would also like to store left over blood and urine for future scientific research, including tests on your genes. This part of the study is optional, so you can still participate in the study if you do not want your left over blood and urine stored long-term.

What happens at the first appointment?

At your first study appointment (called your Screening Visit), with your agreement, a trained study nurse will check your previous blood and urine test results and then explain the study to you. You will have plenty of time to ask questions.

You will then be asked to sign a Consent Form if you agree to take part.

The study nurse will then ask some more details about your medical history and current medication. They will also take a fresh blood sample (about 1 teaspoonful) and collect a urine sample to be sent to the local laboratory for testing.

If you are willing and able to take part in EMPA-KIDNEY, the study research nurse will give you a supply of pills to take for 2-3 months to see if taking extra pills every day is acceptable to you.

The research team will write to and inform your GP to let them know that you are planning to join the study.

This first appointment is the longest appointment and could take up to an hour to complete.

What happens at the second appointment?

2-3 months later, you will have your second appointment (called your Randomization Visit). At this appointment we will check how you got on taking the study pills. You will also be asked if you remain willing to commit to the study for around 3-4 years.

If you are happy to join, a study nurse will perform a short interview, collect another blood sample (about 6 teaspoons this time), ask you to provide a urine sample, and give you your next set of study pills.

This appointment should only take 30-45 minutes to complete.

'Kidney disease is often a slowly progressive condition, so the study needs to be 3-4 years long to definitively answer the study question and have a worldwide impact'

What happens at the other appointments?

Your next appointment (called a Follow-up Visit) will be 2 months later. After that appointment, the study research nurse will see you 4 months later and then every 6 months.

At each Follow-up Visit, the study nurse will ask you about any new medical problems since your last appointment, give you the next supply of study pills and take a blood sample (between 3-6 teaspoons each time) and possibly a urine sample.

Each Follow-up Visit is designed to ideally take less than 30 minutes (although the time needed to collect blood samples and dispense study pills can vary from hospital to hospital).

Following your last study Follow-up Visit, you will stop the study pills. About 4 weeks later, you will be asked to provide one further blood test (about 1 teaspoonful) and a urine sample.

'It is important people in the study take their pills and come to appointments for as long as possible'

What if I don't want to carry on with the study?

We hope you will be able to continue to take the study pills for the full course of the study.

For the study to produce reliable results, it is necessary both for participants to remember to take their study pills as best they can, and for the study team to collect complete information about the health of as many participants as possible.

Your participation is voluntary. It remains your right to decide you no longer wish to, or are no longer able to, participate in any aspect of the study at any time. All data as well as blood and urine samples already collected from you until the time of discontinuation will be kept and used as described below.

If you withdraw, your usual rights as an NHS patient will not be affected in any way.

If you are asked to stop your study pills by a doctor, or you choose to stop them yourself, it would be very helpful if you would allow the study team to stay in touch. To make sure the study produces reliable results we would also need, wherever possible, to continue to collect blood samples at the study clinic for the full trial duration (3-4 years).

You may decide that you no longer wish to come to the study clinic. What would happen in this case is described in more detail below in the section entitled "What are my data protection rights?"

Blood and urine samples

The blood samples you provide will be used to measure things such as kidney, liver, heart function, and levels of blood sugar and salts in your body. The study team want to measure these things to assess the effects of the study pills.

The urine samples will be measured for protein markers of kidney disease and damage.

Some of these tests are not routinely performed by all hospitals, so some of the blood and urine will be transported to Oxford. This is why study blood and urine samples will need to be taken at the study appointments rather than at your GP's surgery.

The study research nurse will also ask you if you would allow left over

blood and urine samples, together with your health data collected in this study, to be stored long-term to help investigate other effects of empagliflozin and other future research (see below).

Leftover blood and urine samples are those which have already been collected for the purposes of the study, and would be discarded otherwise. There is no additional health risk to you. You have the choice whether or not you would like to participate in this optional part of the study. If you decide that you do not want to give permission, you can still take part in the main part of the study.

How much blood will be taken?

The amount of blood will vary at different times during the study but will usually be between 3 and 6 teaspoons of blood each time.

Stored samples and future research

Doctors already know about some of the causes of kidney disease and heart disease. Scientists also think that other factors might play a part, but there is limited understanding of how they work.

In particular, we have limited knowledge about the effect of genes/DNA on the risks of kidney disease, heart disease, strokes, diabetes and a range of other health problems that might be linked to these diseases. These include diseases that your doctor might refer to as metabolic, cardiovascular, infectious or malignant diseases.

If we have your permission to keep your samples, then in the years to come it might be able to make new scientific discoveries using both the information collected in the study and by defrosting and analysing your samples (including testing some or all of your genes/DNA).

With your consent, the blood/urine samples will be stored in a freezer overseen by the University of Oxford for up to thirty (30) years after the study is completed, and will then be destroyed.

All your blood and urine samples will be stored with a unique number, which means you cannot be directly identified from them (i.e. they are "de-identified" from your name and other written personal details about you).

Please note that much like fingerprints, it is theoretically possible to identify someone if your samples are genetically analyzed or if your samples are put together with other data about you. But the chances of successful re-identification by someone without permission to do so are very low because we implement adequate organizational and security measures to protect your data.

For this future research to happen we may need to share your "de-identified" samples with laboratories outside Oxford which can perform specialized tests. Samples may also be sent to Boehringer Ingelheim[1] to process, together with information collected in the study, for the research purposes described above.

Results from this research may also be shared with health regulators.

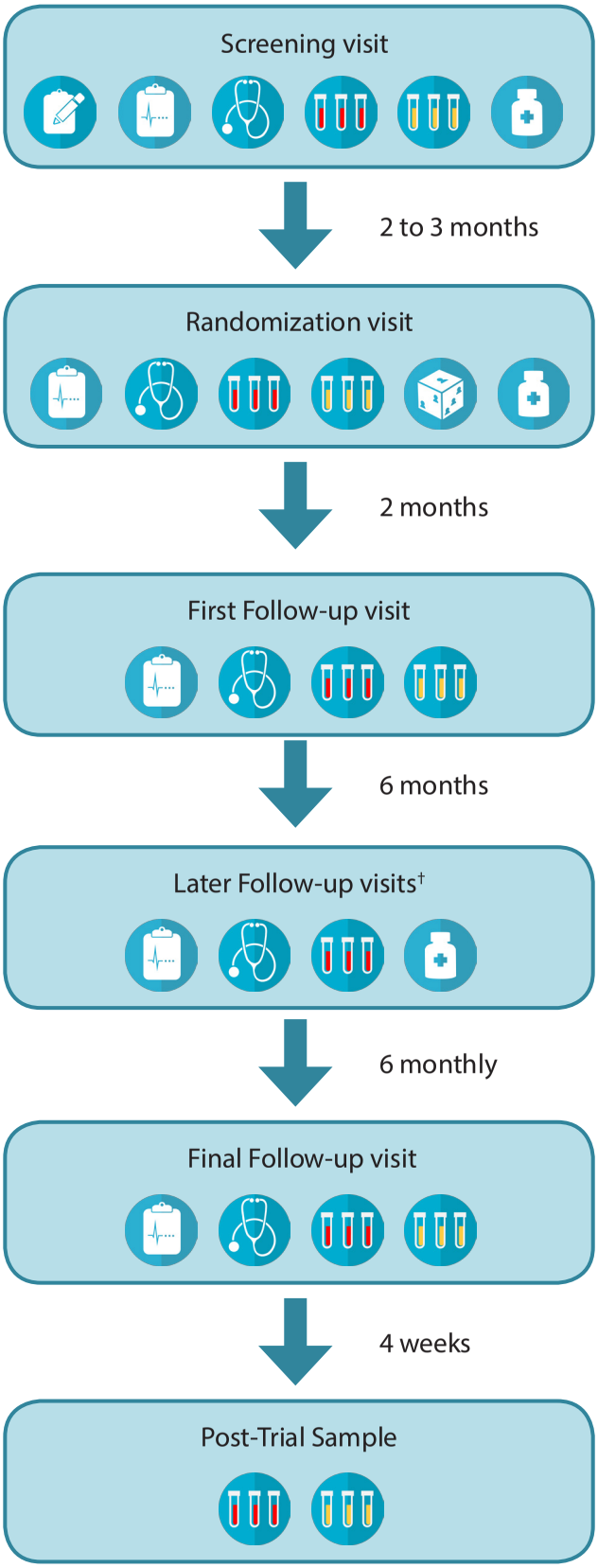
Please note that neither you nor your doctors will be given any information from the analysis of blood and urine samples, including any details of your genes/DNA. In particular, having these samples stored and tested will not affect your ability to get medical or life insurance.

What are the benefits of taking part in this study?

You may be helping yourself, but it is expected that the information from this study may help doctors and scientists to improve treatment

[1] When we say Boehringer Ingelheim, in this case we mean it to also include Boehringer Ingelheim Group of Companies, who may work with other public or commercial private partnerships.

EMPA-KIDNEY Visit Schedule



† urine test at some visits

What might happen at a visit?
Consent form
Questions about the study pills and your health
Physical measurements
Blood sample
Urine sample
Randomization to empagliflozin or placebo
New supply of study pills provided

for people who have kidney disease. If empagliflozin is shown to have benefits, results from this study may help to prevent deaths from heart disease and the need for dialysis or transplantation around the world.

Please note that you are donating your time, information and blood/urine samples, for which we are grateful, but you or your relatives will not be able to receive any financial benefits from any discoveries or products developed using the results from this study or any future research using your health information and data.

Are there any risks?

Most treatments have side effects, which some people may experience, and others may not.

EMPA-KIDNEY is testing empagliflozin, which has already been tested in over 8,000 people. Among these people, it has been generally well-tolerated. It now has a licence from health regulators for use in some types of people who already have type 2 diabetes.

Nevertheless you may experience some symptoms when taking empagliflozin which come from the way the drug works in the body. For example, empagliflozin causes increase salt and water loss into the urine and some people report noticing a need to pass urine more often. Some have reported symptoms suggestive of dehydration, such as increased levels of thirst or feeling faint. It may be necessary to change some of your other pills to compensate. Such symptoms (and other common symptoms) may also happen if you are on the inactive pill (placebo), as they are common in people being treated for a kidney problem or diabetes.

Empagliflozin also works by increasing sugar in the urine. This can occasionally cause pain on passing urine and/or increase the chance of a urine or genital tract infection, like thrush. Confirmed infections are usually easily treated with a course of antibiotics or antifungal pills. If such treatment is ever needed, your GP or local study team could help diagnose and treat you.

Low blood sugar may also occur in people with diabetes who are already taking insulin or certain diabetes pills (like gliclazide). Common low blood sugar symptoms include: sweating, shakiness, hunger, restlessness, slurred speech, and confusion. A sugary drink normally reverses the problem.

For people with diabetes, there is a risk of a condition called ketoacidosis. If you have had ketoacidosis in the last 5 years you cannot join the trial. Ketones build up if there is too little insulin in the body, a situation which also leads to persistently high levels of blood sugar. When taking empagliflozin, ketoacidosis can develop without blood sugar levels being particularly high. The symptoms of ketoacidosis are non-specific, including feeling or being sick, tummy ache and shortness of breath. Others may notice the smell of pear drops or nail varnish on your breath. Ketoacidosis is treated with increased insulin and fluid intake. Hospital treatment with a drip and insulin may be needed. There is extra information available on ketones in a separate information leaflet for those participants with diabetes.

As with all medicines, some people can develop an allergic reaction, including itchy skin or a skin rash. Very rarely, some people may require immediate treatment in a hospital or emergency room for swelling around the mouth and throat causing difficulty in breathing.

Your doctor may also notice that your kidney function slightly decreases on starting empagliflozin. This may be transient and may not be a bad thing as it may be a sign of the protective effect of empagliflozin (or perhaps just natural changes in your kidney function). They may also notice a slight increase in the concentrations of cholesterol and red blood cells in your blood.

Throughout the study, the research team will carefully monitor you and your blood tests for possible side effects. Some side effects may necessitate study pills to be stopped temporarily or permanently.

The study research nurse will keep you up to date with any new important information we learn about the pills.

If you do experience unexpected symptoms and want to ask questions, you can contact your local study research nurse, or an EMPA-KIDNEY study doctor based in Oxford, on Freefone 0808 1644060 (available 24 hours a day, 7 days a week).

What are the other possible disadvantages of taking part?

Although empagliflozin does not appear to cross the placenta, it is possible empagliflozin could affect an unborn child. Women who are pregnant, plan to get pregnant or are breast-feeding cannot join the study. Women who could become pregnant must agree to use highly effective contraception throughout the trial and for a week after the end of the study (types of contraception which are considered highly effective are listed in the footnote below[2]).

If you become pregnant during the trial (or wish to do so), you should stop taking your study pills and tell the local study nurse or study doctor promptly so appropriate action can be taken.

[2] Highly effective methods of contraception include implants, injections, combined oral contraceptive pills (started at least 3 months before joining the trial), intrauterine devices (often known as a coils), vasectomised partner, or true and complete abstinence (i.e. not calendar or temperature methods).

If you have private medical insurance or require travel insurance, your policy may be affected by joining the study, so please check with your insurance provider.

What will happen at the end of the main part of the study?

The results will be published in health or scientific journals, on websites (including www.ClinicalTrials.gov) and will be discussed at major conferences. Others will learn from the results, which we hope will show that more lives can be saved by using empagliflozin. No individual participant will be identified in any report or publication.

We will try our best to inform participants and their GPs of the study results, and any related publicity. We will use study newsletters and videos on the study's website to inform people about what the study shows.

Your contribution to the study could be even more valuable if we have your permission to get information about your health after your very last study appointment. This way we can learn about any longer-term health effects of the study pills. This might include a questionnaire or phone call once a year. Also, the study scientists can continue to get information about your health, such as details from your doctors, NHS Digital (or other central NHS registry) and the UK Renal Registry.

Who is running the study?

EMPA-KIDNEY will be coordinated by scientists from Oxford University's Clinical Trial Service Unit (CTSU).

CTSU is one of the world's leading centres for this type of research. Specifically the study is led by Drs Richard Haynes, William Herrington and David Preiss. They will be supported by many kidney doctors, diabetes doctors and other speciality doctors and nurses around the UK, as well as other parts of the world, to make this study possible.

The EMPA-KIDNEY team has permission from a national ethics committee to do the study in the UK (Oxford C Research Ethics Committee, Ref. No. 18/SC/0155). This committee has checked that the health question being asked is important enough to warrant a study, and that the study is being carried out in an independent, honest and professional manner.

An independent committee of experts also watches over the study and keeps an eye on the progress of the study and safety of the participants. This committee could stop the study early if there was important new information from this, or other, studies which affected whether EMPA-KIDNEY should continue.

Studies such as EMPA-KIDNEY take a very large amount of collaborative effort from many hundreds of research staff around the world and can be costly to run. The study is sponsored by Boehringer Ingelheim, which is also providing the study pills and a grant to the University of Oxford. Those running the study at the University of Oxford also receive support from the UK Medical Research Council and British Heart Foundation to run trials.

How will information be collected about me?

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). These data will be entered into a computer system managed by the University of Oxford and stored securely.

The University of Oxford is a world-leader in developing systems to ensure that information is stored safely for studies such as EMPA-KIDNEY. Only staff with appropriate training and permission can access this computer system.

In addition, the coordinating centre in Oxford will ask for information about your health from your doctors, registries (e.g. the UK Renal Registry), and NHS Digital (or other central NHS bodies). The EMPA-KIDNEY team would send your name, date of birth, NHS number (or CHI number in Scotland) and postcode to NHS Digital (or other central NHS body) who can link this information to individual participants in the study. For participants living in England and Wales, NHS Digital provides information about any cancer on behalf of Public Health England. NHS Digital and other central NHS bodies together provide information about admissions to hospital (called Hospital Episode Statistics) and development of cancer. In addition, they provide information about people who have died. This information may mean the study team does not make contact and cause any distress to relatives, as this information includes date and cause of death supplied on behalf of the Office for National Statistics. Similar information will be requested from the relevant bodies for participants living in Scotland.

What will happen to information about me?

There are an increasing number of data protection regulations that are required to be followed. These laws require us to disclose your rights and how we will use your data.

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 (i.e. they will be the "data controllers"). Both parties are bound by a

duty of confidentiality.

Where the University of Oxford is using your information for research purposes, it will only process personal data as necessary for the performance of such research being carried out in the public interest. This is known under data protection law as our "legal basis" for processing personal data.

In this study personal data that directly identifies you such as your name, address, or date of birth (so-called personal identifiers) can be accessed by the EMPA-KIDNEY doctors and nurses who are running the study at your local hospital. Health regulators (such as the UK Medicine and Healthcare Regulatory Agency and U.S. Food and Drug Administration) 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. These people are also all bound by a duty of confidentiality.

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

In the UK, your name, date of birth, NHS number (or CHI number in Scotland) and postcode will also be stored securely by the University of Oxford to link you with data held by NHS Digital (or other central NHS bodies or the UK renal registry) – see section above. Oxford University will not send these personal identifiers to anyone else (including Boehringer Ingelheim).

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.

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 are to be used for the following purposes: analysis of the study results, to help learn more about how empagliflozin and other "gliflozins" work 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 will provide Boehringer Ingelheim with a copy of the study database containing de-identified data only. It may be necessary for copies of the de-identified database to be shared with health regulators and ethics committees, and it may be shared with other bona fide researchers.

Oxford and Boehringer Ingelheim[3] 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 (i.e. third parties) in the areas of research described above.

Some of the above mentioned parties who receive data will be located outside the UK. 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 (see data protection officer email address below).

The University of Oxford will safely keep the study data and Boehringer Ingelheim will safely keep the copy of the de-identified database for at

[3] Including Boehringer Ingelheim Group of Companies

least 25 years after the end of the study, and perhaps longer if required by the law or other research needs.

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 (see section "What if I don't want to carry on with the study"), 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 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 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.

If you have previously given consent 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 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 correct wrong or outdated personal data and request the deletion of your 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 restrict or object to what we do with your data, or to request that your data be transferred elsewhere. However, sometimes the data controllers may not to 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.

If you are not happy with the way we have handled your data, you have the right to lodge a complaint with the Information Commissioner's Office (telephone 0303 123 1113 or www.ico.org.uk).

What if there is a problem during or after the study?

You have all the usual rights of an NHS patient if you join the study or not.

The University of Oxford has arrangements in place to provide for harm arising from participation in the study. In the unlikely event of your being harmed by taking part, insurance cover is provided by the study sponsor Boehringer Ingelheim International GmbH. Any compensation would be paid in accordance with the guidelines of the Association of British Pharmaceutical Industry.

If you have a concern about any aspect of the study you can speak with the EMPA-KIDNEY team by calling a 24-hour Freefone number: 0808 1644060. If you remain unhappy about the study in other ways and wish to complain formally, you can do this through the NHS Complaints Procedure. You can get details from your local hospital.

Thank you

Thank you for reading this leaflet.

Our aim is to make your participation an interesting and worthwhile experience, while helping us and others to improve the treatment of people who have, or who are at risk of, kidney disease.

EMPA-KIDNEY Appointment Schedule

3 to 4 years in total

	Questions about the pills and your health	Consent Form	Physical measurements (e.g. blood pressure)	Blood sample	Urine sample	Randomization to empagliflozin or placebo	New supply of study pills provided
Screening Visit	✓	✓	✓	✓	✓		✓
Randomization Visit	✓		✓	✓	✓	✓	✓
First Follow-up Visit	✓		✓	✓	✓		
Later Follow-up Visits	✓		✓	✓	(✓)†		✓
Final Follow-up Visit	✓		✓	✓	✓		
Post-Trial Sample				✓	✓		

† Some Follow-up Visits only

If you have any questions you can contact the EMPA-KIDNEY team:

By phone:
24-hour Freephone number:
0808 1644060

By post:
EMPA-KIDNEY
Clinical Trial Service Unit (CTSU)
Richard Doll Building
University of Oxford
Roosevelt Drive
OXFORD, OX3 7LF

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

Or visit our website:
www.empakidney.org

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