Information for participants at the time of scheduled final follow-up visits

The main EMPA-KIDNEY follow-up phase is now drawing to a close. We are incredibly grateful for your participation. Your commitment to a large trial like EMPA-KIDNEY will help clinicians advance our understanding of how to treat kidney disease. Thank you.

Plans to present EMPA-KIDNEY results

The EMPA-KIDNEY team will be processing the information and blood/urine samples provided at final scheduled follow-up visits as soon as we can, and aim to report the trial's main results publicly within a few months (within 2022, wherever possible). Results will be made available to you in the form of summary reports plus an explanatory video on www.empakidney.org. Copies of these summary reports will be available from your site if you do not have internet access.

You and your doctors will also be able to access the EMPA-KIDNEY results at scientific conferences and in medical journals. This will help ensure that the results of the trial become widely known more quickly. If EMPA-KIDNEY shows that empagliflozin is both safe and effective, we will work with government regulators to ensure that it can be prescribed to people with kidney disease who might benefit.

What to do with study pills

Following your final visit you will be asked to stop your EMPA-KIDNEY study pills. Please return any unused pills to your local study team (or a local pharmacy, where allowable). If you return the study pills to a local pharmacy, please inform your local study team so that they can update their records.

Seeing your local doctors after stopping study treatment

Your study team will let your usual doctors know that you have completed the trial. They can discuss any implications for your ongoing treatment at your next appointment.

Your local doctor will not know whether your EMPA-KIDNEY study pills were active empagliflozin or a placebo (dummy pill). We are not routinely providing such information because we would like to follow up participants after the study pills are stopped. This enables assessments of the longer-term effects of empagliflozin on kidney disease. Such post-trial follow-up will provide more reliable results if you, your doctors and the teams at the coordinating centres all remain unaware ("blind") of the contents of your study pills. However, if there is a medical reason for finding out which study pills you were taking, this will be possible and your doctor can contact their coordinating centre.

Additional information about post-trial follow-up plans

Long-term follow-up of participants after the end of a study can provide very valuable information about any longer-term effects of the study pills and help healthcare systems make decisions about the treatments they offer. We are making plans to stay in touch with you after your final follow-up visit to collect ongoing information about your health over the next 2-3 years. This post-trial follow-up will not include any additional visits at your local study site, blood or urine tests, or taking any study pills.

You may recall that during your first trial appointment, we specifically asked for your permission to provide updated information about your health after the scheduled follow-up period as part of the optional consents, and this might include a questionnaire or phone call. This leaflet provides a reminder/update on the study's plans. The post-trial follow-up will collect information about you in the following ways:

1. We will ask your local study team to review your medical notes and/or routine blood tests and provide information on your level of kidney function, whether you have started dialysis, received a kidney transplant, and your current medication.

2. Where possible, we will request information about you from a national or regional registry. In order to link to these registries, we would have to share some information that identifies you, to the people who run the registries (where appropriate consent is available).

3. If we are unable to obtain information from your medical records, or by linking to a registry, we will ask you to complete a short questionnaire once or twice a year (e.g. by telephone or web-based methods).

As for the main phase of the trial, some of your medical records (once de-identified) could be shared with EMPA-KIDNEY doctors overseen by the clinical team in Oxford or checked by other parties (e.g. auditors) to ensure the trial is being performed properly. All these people are bound by a duty of confidentiality. A reminder of your data protection rights and how information about you is handled are available at www.empkidney.org. Note that no aspect of your original consent to join EMPA-KIDNEY is changed by this additional information about the post-trial follow-up and you remain free to stop any part of the study at any time without your medical care or legal rights being affected. **If you change your mind about EMPA-KIDNEY, for whatever reason, please contact your local team.**

If you have any questions please ask your local study team in the first instance. Contact details for your coordinating centre are also provided below.

Contact details for your EMPA-KIDNEY coordinating centre

By phone: 0808 1644060

By post:
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