Queen Mary University of London

SPACE2

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Stopping or continuing RAS-inhibitor medicines before surgery (PROTECT-SPACE II) trial

PARTICIPANT INFORMATION SHEET

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Principal Investigator: [insert PI name]

We would like to invite you to take part in a study called SPACE II, which is part of the PROTECT family of research studies designed to improve care for people who need surgical treatments. SPACE II looks at the care of people taking a common type of cardiac medicine called a RAS-inhibitor, and who are also about to have surgery. The information in this leaflet will help you decide whether to take part. You may want to discuss the study with your friends and family. Please ask us if you have any questions, or if anything is unclear.

Why are we doing this research?

RAS-inhibitor medicines are commonly used to treat high blood pressure, heart failure, and sometimes kidney disease. They sometimes have names that end in -pril (such as ramipril or lisinopril), or -artan (such as losartan, valsartan). Lots of people take these medicines so surgeons and anaesthetic doctors often find that someone who needs to have an operation, for entirely separate reasons, may also be taking one or more of these medicines.

During surgery, doctors want to avoid people developing very high or very low blood pressure because these blood pressure changes can cause other health problems, such as a stroke or heart damage. Because RAS-inhibitor medicines affect blood pressure, doctors must decide whether to ask people to continue these medicines during and after surgery, or to temporarily stop for a few days. We don't know which approach is best, and so different doctors make different decisions. Some doctors ask people to stop their RAS-inhibitor medicine around the time of surgery, while others recommend they are continued as normal. This study will show whether it is better for different patients to stop RAS-inhibitor medicines or continue them, so doctors can give future patients the best advice before surgery.

Why have I been invited?

We are inviting 2,214 people to join the SPACE II study. You have been invited because you are taking a RAS-inhibitor medicine, and you are about to have surgery.

Do I have to take part?

No. It is up to you to decide whether you would like to join the study. If you do decide to take part, you will be asked to sign a consent form. You can stop being part of the study at any time, without giving a reason. If you decide not to take part, or later to withdraw, this will not affect any part of the usual care you receive from your doctors and nurses.

What would taking part involve?

The plan for your surgery will not be affected. If you decide not to join the study, your doctor must still decide what advice to give you about stopping or continuing your RAS-inhibitor. If you do decide to take part, a few days before your surgery you will be randomly allocated (like the toss of a coin) to one of two groups. Neither you nor your doctors will be able to choose which group you are placed in. By taking part in the study, only your RAS-inhibitor medicine will be affected. All other medicine prescribed by your doctor remain unchanged. You will have an equal chance of being placed in one of these two groups:

- Stop group: participants in this group will be asked to stop taking their RAS-inhibitor medicine three days before surgery and start taking it again four days afterwards.
- Continue group: participants in this group will continue taking their RAS-inhibitor medicine as usual.

Before your surgery, we will ask you some questions about your health and take a blood sample (approximately 5ml or one teaspoon). This blood test will be performed in the normal hospital laboratory and tells us about your heart function. Wherever possible, we will use the same blood sample taken as part of your routine care before surgery. If this is possible then no extra blood will need to be taken. A few days before your surgery, we will contact you by telephone and send you a letter to explain what to do with your RAS-inhibitor medicines. We can also send text message reminders to your mobile phone if you choose that. These instructions will explain exactly what to do with your RAS-inhibitor medicine, but you can still contact us using the phone number below if anything is unclear.

When you are in hospital for your surgery, we will come to visit you and look at your medical records to check there are no problems that might affect you taking part in the study. While you are in hospital, you will have three more blood tests on the first, second and third days after your surgery. These measure your heart and kidney function. In most cases, these tests can be added to those taken as part of your routine care. If this is possible then no extra blood

will be taken. If this is not possible, we will collect additional blood samples of approximately 5ml (equivalent to one teaspoon) on each of the three days after surgery. These tests will be performed using the routine blood sampling services at your hospital. No blood samples will be shared outside your hospital and any remaining samples will be destroyed. The results from the blood tests will be anonymised and shared only with the Queen Mary University of London for data analysis purposes.

All of your other treatments will be the same regardless of what we ask you to do with your RAS-inhibitor medicine. Your hospital doctors will know you are in this study. They will monitor you closely throughout your stay and will know how to look after you, whichever study group you join. We will tell your GP you are taking part in the study, so they are kept informed. Most people in the study will be taking their RAS-inhibitor as usual by the time they go home from hospital. Your GP will prescribe this for you, but the hospital can provide a prescription if you have run out.

After your surgery, we will contact you twice more to ask about your health, one month after your surgery and six months after your surgery. This may be by telephone, online, or face to face if you are in hospital. If you have a carer, they would be welcome to help you answer these questions. Your participation in SPACE II will be completed six months after your surgery.

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

If you decide not to take part, or to withdraw from the study later, this will not affect any of the care you receive. You are free to stop taking part at any time and don't need to tell us why. To withdraw you just need to tell us when we contact you, or you can get in touch with us using the contact details below. If you choose to stop taking part in the study, you will remain part of the PROTECT platform, unless you tell us otherwise. We would like to continue collecting information about your health from your medical records and central NHS records. You will not be approached in person for collecting these data. If you do not want this to happen, tell us and we will stop. You can find out what will happen with the data we collect during the study before you agree to take part by speaking with the research team.

What are the possible risks and benefits of taking part?

Because everyone must either stop or continue their RAS-inhibitor medicine when they have surgery, taking part in this study will have similar risks to standard of care. We know that

around one in twenty people who take a RAS-inhibitor medicine will experience a stroke or heart damage after surgery, and around one in ten will experience kidney damage. These complications are usually minor but your doctors and direct care team will carefully monitor you for these complications and treat them if necessary. We don't currently know how these risks vary between people who take RAS-inhibitor medicines for different reasons, such as high blood pressure, kidney disease or heart failure. This is the reason we are doing the SPACE II study.

What we learn from this research will improve the way doctors care for around 500,000 people each year who take RAS-inhibitor medicines and have surgery in an NHS hospital.

How will my information be used?

SPACE II is part of a programme of research called PROTECT which helps us collect your data and keep it safe. Your research team will show you a separate information sheet about PROTECT which explains how we will use your information.

Who is funding the research?

SPACE II is paid for by the UK government through the National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (Reference: NIHR171124).

What will happen to the results of this study?

Once the study is complete, we will share our findings with other doctors and researchers. The results will be published in a scientific journal where anyone can read them for free. We will present our results to doctors and researchers at medical conferences to explain what we found. The results will be available to all hospitals, in the NHS, and worldwide. If you would like, we can send you a plain English summary of our results at the end of the study. We will ask you about this when we record your contact details if you decide to take part.

Further Information

Further information will also be available on the study website: https://www.qmul.ac.uk/protect/studies/space-2

Thank you for taking time to read this information sheet

Your study doctor at [insert hospital name] is:

Name: Phone number:

Address: e-mail:

Your specialist research nurse at [insert hospital name] is:

Name: Phone number:

Address: e-mail:

The contact details for the main SPACE II team are:

Name: SPACE II management team Phone number: + 44 (0)20 3594 0349

Address: Royal London Hospital
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e-mail: space2-admin@qmul.ac.uk

Website: https://www.qmul.ac.uk/protect/studies/space-2