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IRAS 374406

Participant Information Sheet

Evaluating the integration of a guided 3D ultrasound imaging system (CUS) operated by non-specialist staff in a community urology setting

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

At a glance

We are testing a new ultrasound system to see if patients and clinics accept it.

Would you like to get the scan and give feedback? It will take up to 30 minutes.

Taking part is your choice. Your care is the same either way.

The scan is a probe on top of the abdomen. Ultrasound, no radiation.

This scan is extra. It does not replace the other tests you could be referred for.

You can stop at any point, without giving a reason.

What is the purpose of the study?

In this study we would like to find out whether a new type of ultrasound scan, called CUS, can work well as part of a clinic like the one you are attending. The CUS system is a small handheld scanner that guides a trained individual through the scan, and the images are then checked by a specialist doctor (a radiologist or sonographer) at a distance. The results are sent back to

your clinic, and looked over by your clinician. If it works well in clinics like this one, it could mean people get their scans closer to home and sooner, instead of waiting for a hospital appointment. We want to know whether the scan fits smoothly into the clinic's normal work, whether people find it acceptable, and whether its results agree with the standard hospital ultrasound.

Why have I been invited?

We are asking you to think about joining this study because you are attending this clinic for a urological presentation. We are offering people in your situation a CUS scan on top of their normal care, so that we can compare how the new scan performs and how people find the experience. We anticipate recruiting around 260 people in total for this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

It is important to understand that the CUS scan is extra, and completely optional. Whether or not you take part, your standard care will go ahead exactly as planned, and your care at this clinic will not change in any way.

What will happen to me if I take part?

At a glance

1 We explain: a member of your clinic tells you about the study and answers your questions

2 You decide whether you want to take part: even if you booked in to be part of the study, you can opt out at any time, even after signing the consent form

3 The scan: water-based gel and ultrasound probe on top of your abdomen, under 5 minutes

4 A few questions: a short form about how you found it

5 You go home: there is nothing else you need to do for this study

If you are thinking of taking part in the research, you will have the opportunity to discuss it with a member of the team and ask any questions that you might have. If you decide to take part, you will be asked to sign a consent form. You will be sent a copy of the written information and signed Informed Consent form to keep. Please note that, even if you sign the consent form and agree to participate, you can withdraw your consent at any time by contacting a member

of your clinical team, or of the research team. If you withdraw your consent, no further data will be collected from you and any data relating to you will be deleted, except where analysis using your data has already taken place and cannot be undone.

If you take part, you will receive a study ID number, and everything below will happen during your normal clinic visit. Taking part is not expected to add more than 30 minutes to your time at the clinic.

The study will be divided into a few parts.

1. You will have the CUS scan. This is an ultrasound scan, the same type of painless scan used routinely across the NHS: a small amount of gel is placed on your skin and a smooth handheld probe is moved gently over the area being scanned (your lower abdomen). It does not use radiation or needles, and nothing enters your body. The scan will be done by a trained healthcare assistant or nurse from this clinic, guided step by step by the CUS system, which also checks automatically that good images have been captured. The scan itself takes only a few minutes. You can ask for it to be stopped at any point, and it will be stopped straight away. This scan is extra. It does not replace any imaging you could be referred for.

2. After the scan, you will be asked a few short questions about yourself: your age, sex, ethnicity, height, weight, postcode. None of the questions ask anything that could identify you or anyone you know, and your answers are recorded against your study number only.

3. You will be asked to complete a short questionnaire about how you found the experience.

The images from your CUS scan will be looked at by an independent sonographer, in the same way as a normal ultrasound. If anything is found that needs attention, it will be passed to the clinician looking after you through your clinic's usual results process, and they will discuss it with you. If you go on to have a standard ultrasound, the study sonographer will also compare the two scans reports, without knowing who you are, so that we can check how well the CUS results agree with the standard scan.

There is no follow-up visit for this research: your part in the study is finished at the end of your clinic visit.

What will I have to do if I take part?

You will not have to do anything in particular for this study, apart from what is described above. You should still attend your standard ultrasound appointment if planned.

What are the possible disadvantages and risks of taking part?

If you attend a separate study session rather than having your scan at your usual appointment, we can reimburse your reasonable travel costs (up to £20, on receipt). There should be no other disadvantages to taking part, apart from the extra time spent kindly helping us. Ultrasound is a very safe, painless scan in routine use across the NHS; you may feel light pressure from the probe, and the gel can feel a little cold. Please tell us before the scan if you have ever had a skin reaction to water-based ultrasound gel. Occasionally a scan can show something unexpected that needs looking into; if this happens, it will be passed to your clinician

and looked after in the normal way. If you have any concerns about any aspect of this study, then please do not hesitate to contact a member of the study team as below. We will not ask you to do anything you are not comfortable doing.

What are the possible benefits of taking part?

There will be no specific benefits to you from taking part, but the information we will get from you will help us find out whether scans like this can be offered in community clinics, which could help people get diagnosed sooner and closer to home in the future.

What if there is a problem?

If you have a concern about any part of this study, please speak to the research team, who will do their best to answer your questions. You can email the Chief Investigator, Jade Dougoud, at jade@carriertech.uk, or ask a member of the clinic team to contact the research team for you. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the clinic from which you participated in the study.

What if something goes wrong?

Carrier Technologies Ltd (CarrierTech), the sponsor of this study, has insurance in place to cover its legal liability if you are harmed as a result of taking part in this study. This includes a clinical trial liability insurance policy with Markel International Insurance Company Limited (policy number L016647), as well as professional indemnity and public liability insurance.

If you are recruited at an NHS site, the NHS indemnity arrangements will also apply to the care you receive from NHS staff.

If you are harmed during the research and this is due to someone's negligence, you may have grounds for a legal action for compensation against CarrierTech or the organisation where you took part, but you may have to pay your legal costs. The normal National Health Service complaints procedures will still be available to you.

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

Taking part is voluntary. You can withdraw from the study at any time, without giving a reason. Withdrawing will not affect your care in any way, now or in the future.

During your scan: you can ask for the scan to be stopped at any point, and it will be stopped straight away.

After your visit: to withdraw, please contact the study team at the clinic where you took part.

You can also ask any member of the clinic team to pass on your request. Because only the clinic holds the list linking your name to your study number, the clinic will deal with your request. They will tell the study sponsor, CarrierTech, using your study number only, and will confirm in writing that you have been withdrawn.

If you withdraw, we will not collect any more information from you. The data we have already collected will be deleted, unless it has already been used in the analysis and this cannot be undone. You can withdraw your data up until the end of the study, when the list linking your name to your study number is destroyed. After that, your data will be fully anonymous. We will no longer be able to find which data are yours, so they cannot be removed.

If you cannot reach the clinic, you can email the Chief Investigator, Jade Dougoud, at jade@carriertech.uk, and she will put you in touch with the right site.

What will happen to the results of the research study?

At the end of the study, all participants will be sent a summary of the data we find (of everyone together, not data that can identify individuals). We aim to publish the results in a scientific journal that anyone can read for free, and to present them at conferences and to the NHS organisations that plan local services.

Who is organising and funding the research?

This work is organised by CarrierTech Ltd, the company that developed the CUS system, and is funded by the National Institute for Health and Care Research (NIHR) Invention for Innovation (i4i) FAST programme. Because CarrierTech developed CUS, the results of this study matter commercially to the company. To keep the study fair, the scans are checked by an independent sonographer who does not work for CarrierTech, the analysis is independently reviewed, and the results will be published whatever they show.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the London – Brighton & Sussex Research Ethics Committee (REC reference: 26/PR/1161).

Contact for Further Information

Please contact Jade Dougoud: jade@carriertech.uk.

Thank you for taking part in this study!

A copy of this written information will be sent for you to keep.

Transparency Notice

How will we use Information about you?

How will we use information about you?
We will need to use information from you for this research project.

This information will include your:

- Name

- Contact details
- Consent record

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Carrier Technologies Ltd is the sponsor of this study.

Carrier Technologies Ltd is responsible for looking after your information. We will share your information related to this research project with the following type of organisations:

- Healthcare center you attended for the study

We will keep all information about you safe and secure by:

- Only saving this information at the healthcare center you attended for the study
- Access to this information will be limited to the personnel necessary to amend your details or study status
- This information will be saved in a password protected computed location or a padlock protected drawer if physical forms are used

International transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- allow an independent statistician to check and analyse the study results
- support future research, or the development of new tests, medical devices or treatments, by academic institutions or companies (only if you agree to this on the consent form)

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- an independent statistician working in the European Economic Area
- academic institutions and commercial companies carrying out future research or developing new tests, medical devices or treatments (only if you agree to this on the consent form)

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under

UK law. We will make sure your data is safe outside the UK by doing the following:

- the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach
- For this study, your data stays on our secure computer systems in the UK. The statistician can only view it through a secure connection

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for the minimum period of time required by **t**he study to be completed and the results checked, which will be no more than 6 months after the study ends. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- our leaflet www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team

- by sending an email to jade@carriertech.uk
- By contacting our Data Protection Office Jason Carrier at jason@carriertech.uk