ROSSINI 2: Reduction Of Surgical Site Infection using several Novel Interventions

A phase III, multi-arm, multi-stage (MAMS), pragmatic, blinded (patient and outcome assessor), multicentre, randomised controlled trial (RCT) with an internal pilot, to evaluate the use of several in-theatre interventions, used alone or in combination, to reduce SSI rates in patients undergoing abdominal surgery.

SUMMARY INFORMATION SHEET

Version 6.0 14th March 2024

Summary of invitation to take part in the research trial ROSSINI 2.

- Your surgeon has recommended you undergo an operation on your abdomen (tummy). As with any operation, this carries a risk of developing an infection in the cut/ incision (also called a Surgical Site Infection or SSI)

- This hospital is taking part in a research trial called ROSSINI 2, which aims to find out whether using different changes to the normal treatment plan (referred to as 'interventions'), used either separately or in combination, during your operation can reduce the chances of a patient developing an infection.

- It is possible that these interventions might have a combined effect. Our trial will test each method and look in a logical fashion at how they might work together.

- This multi-arm, multi-stage (MAMS) trial has the opportunity to 'drop' (e.g. combinations showing a lack of benefit) and 'introduce' (e.g. combinations based on new, available evidence) interventions at specified time points. MAMS trials aim to answer multiple questions simultaneously within one trial.

- The in-theatre intervention(s) being investigated at present are:
  - A DACC (Dialkylcarbamoyl chloride) impregnated wound dressing to cover the wound for up to seven days after surgery
  - The surgical team changing their Gloves and Instruments during surgery, prior to closing the wound

- If you wish to participate in the trial, you will not get to decide which intervention(s) are used as you will be randomly allocated by a computer. Patients that receive an intervention will form one group, and will be compared to a control group who will undergo their operation in the normal way where no trial intervention is used.

- All patients will have their wounds assessed by a doctor or nurse who is unaware of whether an intervention was used, to see if an infection has developed after their operation.

- You do not have to take part in **ROSSINI 2**, and if you decide not to, no-one will think badly of you and this will not affect the quality of your care in any way.

If you are interested in finding out more about this trial, please continue to read the Patient Information Sheet.

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PATIENT INFORMATION SHEET

Version 6.0 14th March 2024

We would like to invite you to take part in the **ROSSINI 2** research trial. Joining the trial is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it will involve for you. A member of our research team will go through this information sheet with you, to help you to decide whether or not you would like to take part and to answer any questions you may have. Please feel free to talk to others about the trial if you wish.

Part 1 of this Patient Information Sheet (PIS) tells you the purpose of the trial. Part 2 gives more detailed information about what will happen to you if you take part and about the conduct of the trial. Please do take the opportunity to ask any questions you have and to ask for more information if anything is unclear.

Part 1

What is the purpose of the ROSSINI 2 trial?

ROSSINI 2 stands for '**R**eduction **O**f **S**urgical **S**ite **I**nfection using several **N**ovel **I**nterventions 2'. The overall aim is to see if using different interventions during abdominal (tummy) surgery will reduce the chance of you getting a surgical site infection.

What is a Surgical Site Infection (SSI)? How common is it?

A surgical site infection (SSI) is an infection of the incision (cut) made by your surgeon through which the operation is performed. It is also commonly called a 'wound infection'.

The chances of developing an infection vary according to many factors. Some of these are dependent on you as the individual patient, for example if you smoke or suffer from diabetes

your chances of developing an SSI are increased. Other factors include the length of the operation, the exact nature of the surgery and whether it is performed as an emergency or a planned procedure. After abdominal surgery, around one in seven patients will develop an SSI, This rate can increase to one in three if the operation is an emergency.

What are the consequences of developing a Surgical Site Infection (SSI)?

The main problem that patients experience if they develop an infection in their wound is that it takes longer to fully recover and heal. This means they may experience more pain and discomfort than they normally would and this could result in them staying in hospital longer and probably requiring a course of antibiotics. Very occasionally patients need another operation or procedure to deal with a wound infection. In some patients a wound that becomes infected can produce a less tidy scar.

Who is organising and funding the research?

The **ROSSINI 2** trial was developed by the West Midlands Research Collaborative, and is funded by the Health Technology Assessment programme of the NHS research funding charity, the National Institute for Health Research (NIHR). The trial is coordinated by the **ROSSINI 2** trial office at University of Birmingham, Birmingham Clinical Trials Unit (BCTU).

What are the interventions being tested in the Operating Theatre?

If you choose to take part in the trial, you will be randomly selected to receive different interventions or be in the control group. If you are randomised to the control group, this means you will not receive any of the specific interventions we are currently looking at in the trial.

All interventions used in the trial may be tested alone or in combination. They are all interventions which are already used by some surgeons in the NHS, but lack the evidence required to be used for every patient undergoing surgery. We are testing these interventions in different combinations because it is possible that they might have a combined effect. The trial will test each intervention and look at how they might work together.

Please remember that this is a MAMS trial which means that we may 'drop' (or introduce) certain combinations of treatments or even whole interventions at specified time points within the trial. We may even introduce new combinations or interventions at short notice, but a member of the research team will always discuss this with you.

The interventions currently being investigated are:

DACC Dressing – Dialkylcarbamoyl chloride (DACC) impregnated single-use interactive wound dressing to cover the wound for up to seven days after surgery. This is designed to remove any bacteria from the skin surface by attracting them into the dressing pad, and thereby prevent surgical site infections.

Change of gloves and instruments (before fascial closure) – after the main components of the abdominal surgery have been completed, the operating team and scrub nurse will change their gloves for clean ones, and also use new sterile instruments to stitch the abdominal muscles together to close the wound. This may reduce wound contamination and prevent surgical site infection.

What are the possible disadvantages and risk of these interventions?

To the best of our knowledge the additional interventions do not add any further risk to your operation itself. As with any intervention, there is a rare risk of allergy. If you have a documented or suspected allergy to any of the interventions (or its parts) we will not offer you that intervention but you can still participate in the trial.

What are the possible benefits of taking part in ROSSINI 2?

These all have the potential benefit of reducing the chances of you developing an infection in the wound. The alternative possibility is that the interventions will not be of any benefit at all. To the best of our knowledge, none of the included interventions will increase your risk of getting a SSI.

Why are these interventions not used during operations routinely if there is a possibility that they may help reduce infections?

We do not know for definite if these interventions are an improvement on current surgical practice. There have been some similar (although smaller) studies of these interventions which showed encouraging results with decreased rates of infection in patients. However, the studies did not involve enough patients to allow us to recommend that these interventions (alone, or in combination) be used in all patients undergoing abdominal surgery.

Although the interventions are not too expensive, they still add an additional cost to the NHS and we have to be sure that they offer some benefit before starting to use them routinely in everyone across the country.

How have patients and the public been involved in this Trial?

A group consisting of patients and members of the public helped to develop this research topic and the research questions that should be asked.

In designing this trial, we have considered patient opinions on the frequency of participant visits and any tests that we will carry out.

Potential participants were involved in reviewing the Participant Information Sheet and Informed Consent Form, and deciding on the inclusion and exclusion criteria for people taking part in this trial.

Part 2

Why have I been chosen?

The consultant surgeon in charge of your care is involved in the **ROSSINI 2** trial as they feel the trial asks an important question. As such they are inviting all of their patients who are planned to undergo an operation on the abdomen to take part in **ROSSINI 2**. Your surgeon thinks that taking part in **ROSSINI 2** would be a good option to help find out if these interventions work or not. **ROSSINI 2** may include approximately 10,000 people like you from hospitals throughout the UK.

What would taking part in **ROSSINI 2** involve?

If you agree to participate in the trial you will be asked to complete extra questionnaires regarding your wound and its healing as well as information about how you are feeling at various stages throughout your treatment. These details about you will be collected at baseline, before you go home and 30 days after your operation. The local trial investigator(s) will also record some additional information about your medical history and exact operation details. The central part of your involvement in the trial will occur when you are anaesthetised (asleep) for your operation. At this stage we shall contact the Centre for Healthcare Randomised Trials (CHaRT) at The Institute of Applied Health Sciences at University of Aberdeen who will tell us which intervention(s) (if any) to use. After the operation, regardless of which group you were in, the follow-up will be the same. This shall take the form of two formal reviews of your wound to check its healing and assess for any signs of a wound infection. These shall be performed by a doctor, specialist nurse or another trained individual who is not aware which intervention(s) were used in theatre. The first of these reviews will occur before you go home after the operation. The second will be at around 30 days after your surgery. This will either require you to return to hospital or be contacted remotely via a video call or the telephone. This assessment will usually be combined with your routine review after surgery. You will not be reimbursed for any travel costs if you do return to hospital. After this 30-day review, your involvement in the **ROSSINI 2** trial will normally be complete. On the rare occasion that your infection has not resolved by 30 days after surgery, we (at the hospital or from Birmingham Clinical Trials Unit) will continue to contact you via telephone or post for review via questionnaires every 30 days until your wound has healed.

Do I have to take part?

No. Taking part in research is always voluntary. If you decide to take part you will be asked to sign a consent form but you are still free to withdraw at any time and without giving a reason. If you decide not to take part, you don't have to give any reason why and no-one will think badly of you for not wishing to take part. Your care will not be affected in any way. Your surgeon or

local trial investigator will be happy to talk through any questions you may have regarding **ROSSINI 2**.

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

You can decide not to continue with follow-up at any time but, if you do, we would still like your data to remain on file and be included in the trial analysis unless you specifically ask to be excluded.

Can I pick which intervention(s) the surgeon uses?

So that we can find out which intervention(s) are best, the intervention that you receive will be decided for you by a process called randomisation. This gives you roughly the same chance of receiving any one of the intervention(s) or none at all. Neither you nor your surgeon can choose which intervention you receive. This is essential so that a fair comparison can be made between the groups and that characteristics such as age or operation type is the same for all intervention(s). Dividing people into groups in this way is what is called a 'randomised clinical trial' and is the standard and most reliable way of comparing different treatment options.

Who will know which intervention(s)/group I received?

Only the surgeon and the team in theatre will be aware of which group you are in and which intervention(s) were used during your operation. The other doctors involved in your care, as well as the ward nurses and your GP will know that you participated in the trial but not which group were allocated to. There will be no direct mention of this in your hospital notes other than that you are included in the trial. It is important to maintain this secrecy so that when your wound is assessed after the operation, we (and you) are not swayed by knowing if a particular intervention(s) were used during your surgery. This is called 'blinding' of research. Emergency unblinding will only be permitted for medical reasons (e.g. severe allergy), and would be coordinated by the BCTU Trials Office.

Can I ever find out which intervention(s)/group I received?

Yes – Only upon request, at the end of the trial, once the final patient has completed 30-day follow-up and the database is closed will patients be told which group they were allocated to. For safety, if at any time there is a concern about your care which means that a doctor needs to know which intervention(s) were used, they can contact the trial coordinating unit who will be able to discuss this with them and let them know which intervention(s) were used.

What if small changes are made to the trial or new information becomes available?

Sometimes we get new information about one of the interventions being studied. If this happens, your surgeon will discuss how this affects your care and your ongoing participation in the **ROSSINI 2** trial, if needed. You and your surgeon should consider whether you wish to continue in the trial or withdraw. Either way, your surgeon will explain the changes and all other

aspects of your care will continue as normal. If you decide to continue in the trial you may be asked to sign an updated consent form. If the trial is stopped for any other reason, your surgeon would, again, tell you and arrange your continuing care.

What if something goes wrong? What if I get a Surgical Site Infection (SSI)?

It is always possible to develop an SSI after an operation and we cannot guarantee that you will not get one, regardless of whether or not you participate in the **ROSSINI 2** trial. If you do have a SSI, we will administer all standard care as appropriate.

If you have a concern about any aspect of this trial, you should ask to speak to a member of the research team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting <insert details e.g. NHS Complaints Procedure or Private Institutional arrangements>. Details can be obtained from <insert details>.

Will my taking part in ROSSINI 2 be kept confidential?

If you decide to take part in **ROSSINI 2**, we will need to collect information about you and some of this information will be your personal data. Under data protection law, we have to provide you with very specific information about what we do with your data and about your rights.

The University of Birmingham is the sponsor for this trial based in the United Kingdom. The University will use information from you and your medical records and will act as the data controller for this trial. This means that the University of Birmingham is responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the trial, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

More information on how the University processes personal data can be found on the University's website on the page 'Data Protection – How the University Uses Your Data' (http://www.birmingham.ac.uk/privacy/indec.aspx).

Your hospital will use your name, NHS number, date of birth and contact details to contact you about the **ROSSINI 2** trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Individuals from The University of Birmingham and regulatory organisations may look at your medical and research records to check the accuracy of the research trial. Your hospital will pass these details to the University of Birmingham along with the information collected from you and your medical records. The only people at the University of Birmingham who will have access to information that identifies you will be people who need to contact you to complete questionnaires or audit the data collection

process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Your hospital and the University of Birmingham will keep identifiable information about you from this trial for 10 years after the trial has finished.

Your GP and the other doctors involved in your clinical care will also be notified of your participation in the **ROSSINI 2** trial and kept informed of your progress. Also, the research staff involved in the trial may, in the future, access electronic data from your central NHS records, for example through NHS England. This will provide researchers with information that is routinely gathered and stored during your visits to primary care and hospital, and will allow researchers to find out about your health after the trial has ended and the long-term effects of the treatments. By using routinely collected data we will be able to do this without needing to contact you further. In order to do this, we would need to send your name, gender, date of birth and NHS number with any request for information.

The University takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Our staff receive regular data protection training and the University has put in place organisational and technical measure so that personal data is processed in accordance with the data protection principles set out in data protection law. With regards to **ROSSINI 2**, information about your operation and follow-up will be sent by your doctors to the **ROSSINI 2** Trial office at the Birmingham Clinical Trials Unit (BCTU), University of Birmingham on paper and/or electronically, where it will be securely stored. Under data protection law, the legal basis we have to process your personal data is that it is necessary for this research, which is carried out in the public interest. This data will not be used to make decisions about your clinical care.

The manufacturers of all the interventions for the trial will review limited information about any complications experienced by anyone in **ROSSINI 2**. This data will be anonymised and will not identify you.

What will happen to the results of the trial?

Once **ROSSINI 2** has finished we will publish the results in a medical journal so that other patients can benefit. We will also publicise the results on the trial's website www.birmingham.ac.uk/ROSSINI2. No individual patients will be identifiable in any publications. A copy of the published results of the trial will be sent to all patients who have participated in **ROSSINI 2**. In line with clinical trial guidelines, at the end of the trial, the data will need to be securely archived for a minimum of 10 years. Arrangements for confidential destruction will then be made. Should you withdraw consent for your data to be used, it will be confidentially destroyed at that point.

Who has reviewed the trial?

All research in the NHS is reviewed by an independent group of people called the Research Ethics Committee to ensure your safety, rights, wellbeing and dignity. This trial has been reviewed and given favourable opinion by Wales REC 6 Research Ethics Committee.

Where can I get further information?

If you have any further questions about your operation or this clinical trial, please discuss them with your surgeon or local trial investigator, as below:

Name: .....

Tel No: .....

Position: .....

Thank you for taking the time to read this Patient Information Sheet.