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WARWICK
CLINICAL TRIALS UNIT

Meteor2

MENISCAL ALLOGRAFT TRIAL

MENISCAL TRANSPLANT SURGERY OR OPTIMISED REHABILITATION STUDY

You are invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and decide if you would like to take part.

Please ask us if there is anything that is not clear or if you would like more information.

Chief Investigators:
Prof Andrew Metcalfe & Mr Tim Spalding

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BACKGROUND INFORMATION

The meniscus is a firm rubbery curved structure in the knee. There are two of them in each knee, sitting on the edge of the joint.

One of the roles of the meniscus is to cushion impact and protect the joint from wear.

Tears of the meniscus are a common injury, and removing some meniscus (a meniscectomy) is a common operation.

After this operation, most people's pain and symptoms improve. But for some people, the pain and symptoms get worse.

At present, there are various treatment options for people who have pain after a previous meniscectomy.

Possible treatment options include:

<u>Personalised knee therapy:</u>
Physiotherapy - advice on activities and exercises to improve pain and function. The programme may be referred to as optimised rehabilitation.

<u>An operation:</u>
To insert a replacement meniscus taken from someone who has died, this is known as a 'meniscal transplant'.

TRIAL INFORMATION

What is the purpose of this study?

We do not know whether this problem is best treated with personalised knee therapy or surgery to replace the meniscus. Both could improve your pain and reduce restrictions.

Personalised knee therapy and advice can strengthen your knee muscles, reduce pain and improve movement in day-to-day life. There are studies for many similar knee problems to show that patients who have personalised knee therapy have good outcomes.

Meniscal transplant is thought to improve pain and activity by replacing the lost meniscus and provide cushioning to the joint surfaces. There is information from studies showing that people who have a meniscal transplant have good improvements in pain and function and it appears to be safe. However, it has a long recovery period and the operation carries risks associated with surgery.

Right now, doctors do not know whether a meniscal transplant is better or worse than personalised knee therapy (in other words specific physiotherapy and optimised rehabilitation). There is not enough evidence for either treatment in people with this problem at present. In this study, we will answer this by comparing the two treatments so we know which is best for people like you.

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STUDY DESIGN

Study lead & supporting team

MR TIM SPALDING

CO-CHIEF INVESTIGATOR

Professor and consultant knee surgeon at the Cleveland Clinic London Hospital. He has extensive clinical experience managing patients with post-meniscectomy pain both surgically and non surgically.

PROF ANDY METCALFE

CO-CHIEF INVESTIGATOR

Consultant knee surgeon at University Hospital of Coventry & Warwickshire and Professor at the University of Warwick Clinical Trials Unit. He has expertise and experience of leading research studies.




The team include some of the most internationally-recognised experts in physiotherapy, surgery, trials, statistics, and health economics, as well as our patient partners.

The study will take place in NHS hospitals across the United Kingdom and internationally, in Belgium, Canada and Australia. Hospitals taking place will have a lead consultant knee surgeon who will be a supporting member of the trial team.

This research has been organised by the University of Warwick and has been funded by the UK NHS research body, the National Institute for Health Research.

STUDY INFORMATION

Why have I been invited?

You have been invited to take part as you have been identified by your medical team as you have knee pain after previously having some meniscus removed from your knee.

The person treating you thinks that your symptoms might be improved by personalised knee therapy, or by an operation to insert a donor meniscus.

In total, **144** patients, from across the UK and overseas, will be involved in the study.

Do I have to take part?

NO

Participation in this study is completely voluntary and choosing not to take part will not affect you in any way. You can also choose to withdraw your participation without giving a reason by contacting one of the research team.

A decision to withdraw at any time will not affect the care you receive.

If you have a strong preference for one treatment or another, you do not have to take part and can speak to the team at your hospital about the best treatment option for you. If you are pregnant, you can still enter the study although your pregnancy may cause a delay to the surgical treatment. This is what would normally happen in usual NHS care.

STUDY INFORMATION

What will happen if I take part?

If you decide to take part you will be asked to sign a consent form.

In order to make our study work, it is crucial that we have equal numbers of participants in each treatment group. To ensure this is fair, a computer will decide at random which treatment you will have.

Whichever treatment you have, your care will be based on meeting your individual needs and you will continue with the same team of healthcare professionals.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by a NHS research ethics committee, London. It has been reviewed by numerous experts throughout the United Kingdom and by the National Institute of Health Research (NIHR). It has also been reviewed by an independent steering committee who oversee this study.

Before Treatment:

You will be asked to complete a questionnaire about your knee and your general health.

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STUDY INFORMATION

Which Treatment?

PERSONALISED KNEE THERAPY

If you are allocated to the personalised knee therapy group:

You will receive a personalised rehabilitation course that has been specifically designed to treat people with this problem.

Expert physiotherapists have developed an optimised rehabilitation programme so that you will have the best chance of improving your knee.

Instead of a standard set of exercises, each therapy course will be unique to you, as it will be tailored to your needs by a senior physiotherapist.

You will be assessed in a one-to-one visit by a senior physiotherapist at <<Site name>>, to design a treatment plan.

If we think you would benefit from a brace or any other device, we will help organise this for you.

On-going treatment will remain at the specialist hospital, or if this is a long way from your home, we will refer you back to your local physiotherapy department and send them instructions regarding your treatment.

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STUDY INFORMATION

Which Treatment?

MENISCAL ALLOGRAFT TRANSPLANT

If you are allocated to the meniscal transplant group:

You will be placed on a waiting list for an operation at <<site name>>.

The operation itself is either done using keyhole surgery, with small cuts over the knee, two that are 2-3cm, and two that are 1cm, or through a small open incision of around 8-10cm.

Once inserted, the transplant will be held in a position by strong stitches.

The new meniscus is from someone who has died recently, they are carefully checked to ensure they have not had any infectious diseases.

After surgery, you will be given crutches to help you walk and then will have some physiotherapy to help you recover from the operation.

Both treatments will be subject to NHS waiting lists. The wait for a meniscal transplant can be variable, even in places with normally short waiting lists, as the surgeons have to wait for a transplant of the right size to be available. This can be quick or it can take many months.

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STUDY INFORMATION

Follow Up

Step 1

Once you have joined the study you will be contacted by the Warwick study team at **3, 6, 12, 18, and 24 months** to complete a questionnaire. We will seek future funding for long-term follow-up at five and ten year until September 2035. Just before your surgery or personalised knee therapy you will also be asked to complete a one-off additional questionnaire which will be provided to you by the research team at site.

Step 2

You will have a choice as to how you want to complete your follow-up questionnaires. This can be done either via an App or on paper which can be posted back to us in a freepost envelope.

If you choose to complete your questionnaires via the App your phone number and email address will be provided to the app developers so they can send you links and reminders about the questionnaires.

The Warwick study team will use your phone number and/or email address to contact you about upcoming questionnaires, any new information, and long term follow up.

Step 3

If you need help completing your questionnaire at any time point, please contact a member of the trial team to assist you through the process.

Your travel costs will be reimbursed to you in the form of a £30 E-voucher which you will receive at baseline, 12 and 24 months. We will need your email address to send this to you.

What are the possible benefits of taking part?

Both treatments are designed to help reduce the symptoms you currently feel in your knee. By taking part in the trial, you are helping to decide about the best treatment for people in the future.

What are the possible disadvantages of taking part?

There are no other risks over and above what your doctor would normally inform you about.

Personalised Knee Therapy:

The risks associated with personalised knee therapy are also the same for patients that do not take part in the study. These may include temporary muscle soreness from exercise. A knee brace may be offered as part of both personalised therapy and they are routinely used in recovery from surgery. They may provide good pain relief and are important after surgery to protect the recovering tissues. They may be uncomfortable or inconvenient.

The personalised knee therapy programme is likely to be a shorter wait compared with surgery. We do not know which treatment would give a better improvement in the long term, that is what this study is trying to find out.

Meniscal Allograft Transplant Surgery:

There are risks with meniscal allograft transplant surgery, including surgical risks of tearing the new meniscus, persistent knee pain, infection and blood clots, but these are the same risks for patients that do not take part in the study. The risks of the operation will be discussed in more detail with you by the clinical team who are looking after you in hospital, as part of your consent to treatment.

FURTHER INFORMATION

Are these new treatments?

Both of these treatments are already used within the NHS. However, it is important to perform research that compares one type of treatment to another so that we can offer the best possible treatment in the future.

What happens when the study ends?

You will be in the study for 24 months. However, we will seek future funding for long-term follow-up at five and ten years until September 2035. With your consent, NHS England, other Central UK NHS bodies or other country specific equivalents may be used to help contact you or provide information about your health status for this follow-up.

When we have enough people in the study to answer the question, we will stop entering new people into the study. If you have consented but the study ends before you have had your operation, your surgeon will decide what treatment option may be best and offer that to you.

What if new information becomes available?

Sometimes during the course of the research project new information becomes available about the treatment that is being studied. If this happens, your consultant will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw , your surgeon will make arrangements for your care to continue. If you decide to continue, you will be asked to sign an updated consent form.

DATA MANAGEMENT

What happens to the results of the research study?

At the end of the study we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications resulting from the study.

Once all participants have been followed up and the results analysed, we will make a copy of the study results available which will outline what was found during the study and make them available for you by post via an end of study letter and by listing it on the trial website.

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick Official, entirely independent of this study or the Independent Advice Service/PALS service (Patient Advice Liaison Service) at your participating site:

Deputy Director/ Head of Research Governance

Research and Impact Services
University House
University of Warwick
Coventry
CV4 8UW

Tel: 02476 575733
Email: *researchgovernance@warwick.ac.uk*

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: infocompliance@warwick.ac.uk

If you are not satisfied with our responses or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)

Patient Advice Liaison Service

<<Site Patient Advisory and Liaison Service Office Details>>

Email:

How will the University of Warwick use my information?

- Individuals from the University of Warwick and regulatory organisations may look at your medical and research records to check the accuracy of the research study. This information will include ethnicity, race and health information, which is regarded as a special category of information. We may use this anonymised information for future research. The basis for processing your special category personal data is Article 9(2j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.

- The only people in University of Warwick who will have access to information that identifies you will be people who need to contact you to follow up on the progress of your recovery, contact you regarding 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 or contact details however IT administrators will have access to this information.

- Your personal data will be processed for the purposes outlined in this notice. The legal basis that would be used to process your personal data is Article 6(e) a task in the public interest. In addition to the legal basis for processing personal data, the University of Warwick must meet a further basis when processing special category data, including: racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data, data concerning health, data concerning a natural person's sex life or sexual orientation.

- The data controller for this project will be the University of Warwick. The Information and Data Compliance Team at Warwick will provide oversight of activities involving the processing of personal data, and can be contacted via infocompliance@warwick.ac.uk.

DATA MANAGEMENT

How will hospital sites use my information?

- Hospital sites will collect information for this research study from you, your medical records and your treating physiotherapists and will pass these details to the University of Warwick. Queries may be returned to the site to ensure accuracy of the collected information.

- Hospital sites and the University of Warwick will use your name and contact details to contact you about the research study, to make sure that relevant information is recorded for your care, and to oversee quality of the study. If we are unable to contact you, we would like to be able to contact your next of kin. We will therefore request contact details of two additional people, but you can only provide us with their contact details if you have their permission to do so. If you agree to take part, your GP and other doctors who may treat you, may be notified that you are taking part in this study.

- NHS sites will keep identifiable information about you from this study for 10 years after the study has finished.

How will my Recovery App use my information?

- There is the option for you to complete data collection via an App called MyRecoveryApp. The company who provides this App are called Future Health Works. MyRecoveryApp will only use your name, contact details, or next of kin contact details to contact you about the study, to make sure that relevant information is recorded for your care, to oversee the quality of the study, and approach you about long-term follow-up.

- The data collected via this App for the purposes of this study will be stored on several servers: London (UK) for participants recruited in UK and Australia, Northern Virginia (USA) for participants recruited in Canada, and Paris (France) for participants recruited in Belgium.

- Your data (including personal data) will be removed from their records once we have completed the final follow up of the final participant. Future Health Works' privacy statement can be found here: https://appsupport.team/privacy-uk-en/

DATA MANAGEMENT

Will my taking part in this study be kept confidential?

- The University of Warwick is the sponsor for this study, based in the United Kingdom, and will act as the data controller. This means that the University of Warwick are responsible for looking after your information and using it properly. The University of Warwick will keep identifiable information about you for 10 years after the study has finished. 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 study, 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. Please follow the link below to find out how the University of Warwick handle your personal data processed in connection with the study:

https://warwick.ac.uk/services/idc/dataprotection/privacynotices/research

Where can I find out more about how my information is used?

You can find out more about how we use your information at:

- www.hra.nhs.uk/information-about-patients/
- By asking one of the research team
- By sending an email to meteor2@warwick.ac.uk

DATA MANAGEMENT

Contacts for further information:

If, at any time, you would like further information about this research project please contact:

Site contact information:
<<Site METEOR2 Study Team Details>>

Scan Me

Trial contact information:
Email: meteor2@warwick.ac.uk
Website: www.warwick.ac.uk/meteor2

Thank you for considering participation in this study and for taking the time to read this information sheet.