**Participant Information Sheet and Consent Form**

TITLE: A randomised trial of colchicine for osteoarthritis of the hand

PROTOCOL NO.: COLAH

INVESTIGATOR:Prof Catherine Hill

 The Queen Elizabeth Hospital

 28 Woodville Rd, Woodville South

**STUDY RELATED**

PHONE NUMBER(S): Carlee Ruediger

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1. **Introduction**

You are being asked whether you want to participate in a clinical research study because you have osteoarthritis of the hand. First we want you to know that taking part in a clinical research study is entirely voluntary. Second, you need to know that there are important differences between being cared for in a clinical research study and being cared for by your doctor outside of a clinical research study. Being in this study does not replace your regular medical care. The purpose of regular medical care is to improve or stabilise your health. The purpose of a clinical research study is to gather information. A clinical research study is designed to answer specific questions about a medication's safety and its effect on a disease or condition. Therefore, it is important that you understand the difference between the regular care you receive from your doctor and what is involved in the clinical research study and why the clinical research study is being done.

This consent document gives you important information about your potential involvement in the clinical research study. Please read this information carefully before deciding to take part. No one can make you take part and you can stop at any time. If you choose to take part in this research study, you will need to sign this consent document and you will receive a copy of this signed and dated document for your records.

Please read through the entire Participant Information Sheet before you make your decision about participation. However, if you would like to go through certain sections again, you can use the below indexing of pages to help you find that information:

|  |  |
| --- | --- |
| Background to this research   | Pages 1-2 |
| Details for each visit  | Pages 3-8 |
| Medication information | Page 9 |
| Participation | Page 10 |
| Risks with study drug and procedures | Pages 11-13 |
| Your rights as a participant/ privacy/ compensation | Page 13-15 |

Purpose of the Study

Osteoarthritis (OA) of the hand is a disorder characterized by bone changes, progressive loss of cartilage and joint space narrowing. Hand OA is a common disease, with up to 20% of older Australians having painful disease. Those who suffer from hand OA are likely to suffer from pain, significant physical disability, and reduced quality of life. There are no proven drug treatments that improve pain or slow progression of the disease. Patients with osteoarthritis of the hand who also have inflammation in the joints (also called synovitis) have more pain and are also more likely to develop joint damage. This is approximately 50% of patients with hand OA. With an ageing population, the burden and health-care costs related to hand OA will increase.

Currently, there are no proven medicines for the treatment of hand OA. The lack of classification of hand OA according to inflammatory characteristics may have contributed to previous negative outcomes in clinical trials. Current treatments of patients with Hand OA include medicines such as paracetamol, ibuprofen and other Non-Steroidal Anti-inflammatory Drugs (NSAIDs), topical agents which seeks to reduce the pain caused by OA. Cost-effective therapies targeting synovitis may offer a novel approach for reducing disease burden from hand OA.

This study of colchicine versus a placebo in hand OA with synovitis is planned to determine whether this drug will be effective at reducing pain in hand OA. It is estimated that 60 patients will be required for the study. If positive, then further studies to determine whether the drug also reduces x-ray progression in hand OA would be appropriate.

Colchicine is a low cost drug which has long been used in the anti-inflammatory treatment of acute gout.. The primary mechanism of action of colchicine is to down-regulate multiple inflammatory pathways and alter the immune pathways. Preliminary studies in knee OA have indicated that colchicine may have a beneficial effect on pain and a larger randomized clinical trial of colchicine in knee OA is currently underway. No studies of colchicine have been undertaken in hand OA.

The following sections describe the clinical research study. Before you decide to participate, please take as much time as you need to read the information carefully and ask questions and discuss with the study site staff, with your family and friends, or with your personal physician or other healthcare professionals. The study site staff will explain and answer any questions you have before you make a decision.

1. **HOW LONG WILL MY PARTICIPATION IN THIS STUDY LAST?**

The maximum length of participation will be 24 weeks, including the initial screening periods, and the 4 week follow up after stopping the trial medication.

1. **WHAT WILL HAPPEN BEFORE THE CLINICAL RESEARCH STUDY BEGINS?**

Your participation in this study is entirely voluntary. It is up to you to decide whether to take part or not. If you decide to withdraw from the study or not to take part your future medical care will not be affected in any way.

**If you do decide to take part, you will be asked to sign this consent form and you will be given a signed copy of the consent form to keep. You are free to leave the study at any time without giving a reason.**

1. **WHAT WILL HAPPEN DURING THE STUDY?**

The study will begin with you signing and dating the informed consent form, and study procedures will be carried out in the following time periods:

* The first part of this study is called a Screening Period (which begins at your first visit (Visit 1). During this period, the study doctor will decide if you qualify to participate in the study. If you do not qualify for the study you will not proceed in the study.
* The next visit will be a Baseline visit or week 0. If based on the results of the tests and procedures from Visit 1 (screening) you qualify to continue participation in the study. From this visit you will begin taking double-blind study medication, which will be either COLCHICINE or placebo. "Double-blind" means that neither you nor the study doctor will know what treatment medication you are getting. VAS pain and AUSCAN questionnaire will be completed at the beginning of the study as a baseline, along with Grip strength in the study hand and measure your hand joints for tender and swollen joints.
* Over the following 12 weeks you will have follow up blood tests at your local SA pathology blood rooms (which you will be given forms for at baseline) and phone calls from the study coordinator to follow up your progression through the study as well as any adverse events you may have had. At these times you will be asked if your medication doses have changed or if you are taking any new medications. At week 6,12 and 16 a further VAS pain and AUSCAN questionnaire will also be completed, This may be via a phone call from the study coordinator (week 6 and 16)
* At week 12 you will be asked to return to the Queen Elizabeth hospital for a repeat hand ultrasound, Grip strength, tender and swollen joint count, VAS pain and AUSCAN questionnaire and at this time you will stop the colchicine. A safety phone call 4 weeks later will also include a VAS pain and AUSCAN questionnaire and this will be the final study visit
1. **STUDY PROCEDURES**

If you agree to be in the study and qualify to participate based on the screening assessments, you will be randomly assigned by chance (like the flip of a coin) to one of the following groups:

* COLCHICINE tablet twice daily for 12 weeks
* Placebo tablet twice daily for 12 weeks

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Visit** | **1** | **2** | **3****Phone Call** | **4** **Phone Call** | **5** **Phone Call** | **6** | **7** **Phone Call** |
| **Week** | **screen** | **0** | **3** | **6** | **9** | **12** | **16** |
| **Informed Consent****Clinic measurements** | **X** |  |  |  |  |  |  |
| Physical measurementsa | X | X |  |  |  | X |  |
| Hand xray | X |  |  |  |  |  |  |
| Hand ultrasound | X |  |  |  |  | X |  |
| Blood tests  | X |  |  |  |  |  |  |
| FBE/ECU/LFT/CK/CRP\* |  | X |  | X |  | X |  |
| Pill counts |  |  |  | X |  | X |  |
| **Phone Call** |  |  | X | X | X |  | X |
| **Questionnaires** |  |  |  |  |  |  |  |
| VAS-pain | X | X |  | X |  | X | X |
| AUSCAN questionnaire *[12]* |  | X |  | X |  | X | X |
| Safety (AEs) |  | X | X | X | X | X | X |
| Medication diary | X | X | X | X | X | X | X |

a Full physical examination, blood pressure, tender and swollen joint count (hand only), height, weight, waist circumference, grip strength. Loose clothing should be worn on physical exam days, allowing to have shirt lifted.

You will receive all of your medication (either colchicine or placebo) at the beginning of the study (Study visit 2). A Placebo tablet is an identical tablet to study drug which does not contain an active drug ingredients. You will be required to count the amount of tablets you have at home remaining at the week 6 phone visit to check for drug compliance. You will be asked to bring any remaining tablets and empty containers with you at the week 12 visit. In case of an emergency the information of what arm of the study you are randomized to will be available.

If you experience an injury or increased pain (flare) due to your osteoarthritis, use of pain relief such as paracetamol or ibuprofen may be used. You will need to track your use of these medications and the usage length in your medication chart provided at the baseline visit.

**Visit 1 – Screening**

After reading and signing this informed consent document, the following tests and procedures will be performed to determine if you qualify to participate, this visit will take approximately an hour:

* Review of inclusion/exclusion criteria
* Collect personal information from you, such as your initials, date of birth, sex, and race
* Review of your medical and medication history. You may be asked to provide permission for the study doctor to obtain copies of your medical records from your primary care physician.
* Physical exam including an assessment of your weight, height, waist circumference and vital signs (blood pressure, heart rate, breathing rate and temperature). This may require you to have your shirt lifted to check your chest loose clothing should be worn on physical exam days, to allow for this. No further undressing will be required., No further undressing will be required.
* The study doctor will assess your osteoarthritis symptoms ( complete a joint count)
* Grip Strength of both study and non-study hand will be completed
* A blood sample will be collected (15 mL) and a urine sample (about a half cup, 100 mL) for clinical laboratory tests.
* You will be asked to complete a questionnaire to assess how you are currently feeling.
* You will be scheduled to have an x-ray and an ultrasound of your hand. Both of these procedures will be conducted before you return for Visit 2. The x-Ray and ultrasound will confirm the presence of your osteoarthritis.

After this visit, you will be told whether you qualify for the next part of the study.

**Visit 2 – Baseline Visit**

Your second visit will take place once x- ray and ultrasounds from Visit 1 are complete and this may take 1-2 weeks. During this visit the following procedures and tests will be performed, this visit will take approximately 30 minutes:

* Review any changes in your health or medications since your last visit.
* Review of inclusion/ exclusion criteria
* Go over your use of medications.
* Vital signs (blood pressure, heart rate, breathing rate and temperature)
* Completion of questionnaires to evaluate your pain and symptoms of osteoarthritis, and how they affect your activities of daily living.
* After completion of the above procedures, if you are found eligible to continue in the study, you will be randomly assigned either to COLCHICINE or to a matching placebo. As explained above, neither you nor your doctor will know if you are taking COLCHICINE or placebo since both will look the same.
* At this time you will also be given a blood form to have further blood tests completed in line with visit 4 (week6)

**Phone call Visit 3 / 5 – (week 3 / 9)**

This visit will be done via a phone call; this will take approximately 15 minutes

* Review any changes in your health or medications since your last visit.
* Assess any adverse events

**Visits 4 – (week 6)**

This visit will be done via a phone call; this will take approximately 15 minutes

* Review any changes in your health or medications since your last visit
* Completion of questionnaires to evaluate your pain and symptoms of osteoarthritis, and how they affect your activities of daily living
* A count of the medication taken / remaining ( by you)
* Assess any adverse events

**Visit 6 (Week 12)**

This visit will take place at the Rheumatology unit at TQEH and will take approximately 30 minutes

* Physical exam including an assessment of your weight, height, waist circumference and vital signs (blood pressure, heart rate, breathing rate and temperature). This may require you to have your shirt lifted to check your chestloose clothing should be worn on physical exam days, to allow for this. No further undressing will be required.
* The study doctor will assess your osteoarthritis symptoms ( complete a joint count)
* Grip Strength of both study and non-study hand will be completed
* Review any changes in your health or medications since your last visit
* Completion of questionnaires to evaluate your pain and symptoms of osteoarthritis, and how they affect your activities of daily living
* You will be scheduled to have an ultrasound of your hand.
* A count of the medication taken / remaining (you will not be given back any remaining colchicine from this visit any remaining will be returned to pharmacy for destruction)

Phone call **Visit 7 (week 16 -Final Study Visit)**

After Visit 6 you will receive a phone call one month later for your final visit

* Completion of questionnaires to evaluate your pain and symptoms of osteoarthritis, and how they affect your activities of daily living. ( completed via phone call)
* Review any changes in your health or medications since your last visit
* Assess any adverse events
* Colchicine will not be available at the end of the study.

**Early Termination Visits**

If you choose to discontinue taking study medication for any reason from the study, you will be asked to return to your study doctor for a final visit and final procedures. It is important for your health and safety to have this last visit. Your study doctor will talk to you about any potential medical issues that may arise and arrange for you to receive alternative treatment for your condition.

1. **WHAT ELSE SHOULD I KNOW ABOUT THE STUDY PROCEDURES?**

**Ultrasound**

Hand ultrasounds will be done at screening and at 12 weeks, there is no known risk to an ultrasound, this may cause some discomfort at the time of the scan as there will be some pressure on your arthritic joints.

**Grip Strength**

Using a dynamometer we are able to test the strength of your grip. This will be completed at baseline and the week 12 visit

The participant holds the dynamometer in the hand to be tested (starting with the unaffected (non-study) hand for pain free grip force), with the elbow extended and the forearm pronated (since this position was thought to be the most sensitive for testing). The participant squeezes until they can just start to feel the pain but no harder for 5 seconds. No other body movement is allowed. No encouragement is given. There will be some pressure on your arthritic joints which may cause discomfort.

**Blood and Urine Samples**

At visit week 1 and 12, 15 ml blood and 100 ml urine samples will be taken. There is a possibility that your study doctor may ask to take an additional blood and / or urine sample from you if they feel it is needed in order to properly evaluate the results of the tests conducted on these samples.

Your samples will be tested locally at SA pathology. All samples will be destroyed once all tests are complete. The samples will only be used for study related purposes, and no other analyses than study related analyses will be performed.

If additional analysis is proposed, your consent will be required. You will have the right to refuse to these additional tests or analysis being carried out and you may at any time request for any retained, identifiable samples to be destroyed.

These samples will not be used for genetic or DNA testing.

HOW WILL I RECEIVE THE STUDY MEDICATION?

The study medication will be presented as hard white or off-white tablets. Each active study medication tablet will contain 0.5mg Colchicine. Matching placebo tablets will contain the same ingredients as the active study medication, except that Colchicine will be replaced by an equivalent quantity of non-animal sourced cellulose (inactive substance). All the study medication will be given to you at the 2nd visit (baseline).

Colchicine is currently Therapeutic Goods Administration (TGA) TGA approved for “the relief of pain in acute gout”. It is not currently TGA approved for the use in OA.

1. **WHAT HAPPENS WHEN I FINISH TAKING THE STUDY MEDICATION?**

Your regular medical care might include some of the study tests and procedures. The study doctor or a member of the study staff can answer any questions you may have about which tests and procedures are not part of your regular medical care.

After the study is over, you should talk to the study doctor about your future treatment for osteoarthritis.

1. **ARE THERE ANY SPECIAL INSTRUCTIONS TO FOLLOW WHILE PARTICIPATING IN THIS STUDY?**

**While you are in the study, you must:**

* Follow the instructions you are given by the study doctor and study staff.
* Come to the study centre for all visits with the study doctor or study staff as scheduled.
* Always contact the study doctor or the study staff before you start taking ANY new prescription or over the counter medication since some medications are unsafe to be taken together with the study medication
* Tell the study doctor or study staff if you want to stop taking study medication or stop being in the study at any time (you do not need to provide a reason for discontinuing treatment or stopping your participation in the study if you do not want to).
* Take your study medication as prescribed and return all study medication bottles
* You will be required to carry a patient card with information about your participation in the study and emergency contact information for the study staff.

It is possible that taking Colchicine with your regular medications or supplements may change how Colchicine, your regular medications, or your regular supplements work. Please inform your study doctor if you start, stop, or have any changes in medications that you take, including over-the-counter medications (for example, allergy medications, cough and cold remedies, or pain relievers), herbal supplements, vitamins and minerals, as well as medications you receive as a prescription, before or during the study.

You must not currently be participating in a study involving an investigational medication or have received an investigational medication within 30 days from the Visit 2.

You must tell your study doctor if you have been sick or injured or if there have been any changes in your treatments and medications during the study.

1. **VOLUNTARY PARTICIPATION AND WITHDRAWAL**

Your participation in this study is voluntary. If you decide not to participate in this research study, or if you decide to withdraw from the research study later on, it will not affect your future treatment, nor will there be penalty, prejudice, or loss of any benefits to which you are otherwise entitled.

You may also choose to discontinue taking study medication at any time, but continue to go to the study visits and have the procedures done. This will help with the study as all the information collected is valuable to determine the safety of the study medication.

Should you decide to participate in this research study, you may discontinue participation at any time, for any reason. Should you decide to withdraw from the research study for any reason, please contact the study doctor immediately. You will be asked to see the study doctor or designated study staff for an Early Termination Visit to collect information that may be important for this study, as well as to ensure your safety. You will be given a telephone diary at your baseline visit to document know when you will be expecting called regarding the study (week 3, 6, and 16)

If you withdraw or are removed from the study, biological samples (blood or urine samples) that have been collected from you (but not yet fully analysed) will be. However, any data already generated from your samples will be kept to preserve the validity of the study.

Your participation in this study may be discontinued at any time with or without your consent by the study doctor. This could occur if your study doctor considers it to be in your best interest, you do not follow instructions given to you by your study doctor, or if you suffer a complication. This could also happen if your study doctor ends the study.

**NEW FINDINGS**

Your study doctor will inform you of any significant new findings that may develop during the course of this clinical research study that may affect your willingness to continue as a participant in this study. Significant findings will require reconsenting to the study.

1. **WHAT ARE THE RISKS AND POSSIBLE DISCOMFORT OF BEING IN THIS RESEARCH STUDY?**

Some adverse reactions (harmful effects of medication) can be expected with medication such as Colchicine and some were reported by subjects treated with Colchicine in prior trials. Colchicine has been used for many years and is commonly used for treatment of gout.

**COLCHICINE IS TO BE TAKEN WHOLE WITH A FULL GLASS OF WATER**

*Some of the most common side effects*

* Nausea, vomiting, stomach pain and diarrhea
* Loss of appetite

*Less common possible side effects*

* Skin Rash or Hair loss
* Severe diarrhea with bloody or black tarry stool
* Difficulty with passing urine or blood in urine
* Confusion
* Numbness or weakness in the fingers or toes
* Bleeding, brushing, mouth ulcers or infections (more common in high doses taken for acute gout or when taken for a long time)

*Rare side effects*

Headache, dizziness, difficulty sleeping, seizures, convulsions, tremor, shortness of breath and muscle weakness

Very rarely, death has occurred when colchicine has been taken in overdose.

Risks of Allergic Reaction

Sometimes people have allergic reactions to medications. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction are:

* Shortness of breath
* Wheezing or difficulty breathing
* Swelling of face , lips or tongue
* Skin rash, itching or hives.

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study. If you feel you are having a severe allergic reaction you should get urgent medical help by dialing 000 or attending a hospital emergency department.

**Risks of Taking Placebo**

Some people in the study will get placebo instead of Colchicine. Taking placebo is the same as not taking anything for your osteoarthritis. If you take placebo during the study, it is possible that your osteoarthritis symptoms may get worse. Please ask the study doctor or study staff if you have any questions about placebo.

**Stopping Your Regular Medications**

You will not be asked to stop any of your regular medication during this study. Documentation of any medications other than regular medications used will be documented in the Medication diary given at the baseline visit

**Risks of x-ray**

This research study involves exposure to a very small amount of radiation. As part of everyday living,

Everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) per year. The effective dose from this study is about 0.002 mSv. At this dose level no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be very low.

**Other Risks**

There are also potential complications resulting from having blood samples taken from your arm. These include pain, bleeding, inflammation of the vein, bruising, light-headedness, and, on rare occasions, infection. This study may involve risks that are currently unknown, so it is important you tell your study doctor of any illnesses and conditions you experience.

There may be risks or side effects which are unknown at this time.

**RISKS OF PREGNANCY**

**WOMEN**

The effects of Colchicine on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project.

For female participants:You must use a highly effective form of birth control for 4 weeks before you start receiving study medication and while you are taking part in the study.If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

**MEN**

If you are a man, there may be risks to an unborn baby you father during or after the study. The study doctor will talk to you about the birth control options you and/or your partner must use during the study. If you are male, you should not father a child or donate sperm for at least 3 months after the last dose of study medication.

Both male and female participants must use highly effective contraception during the course of the research and for a period of 3 months after completion of the research project. You should discuss methods of highly effective contraception with your study doctor.

**PREGNANCY FOLLOW -UP**

Should you become pregnant during the study you must report it immediately to the study doctor. If this happens, the study doctor will discuss with you what you should do. If you should become pregnant, it is expected that you will obtain and follow good prenatal and postnatal care. You will be responsible for all routine pregnancy-related expenses.

1. **WHAT OPTIONS ARE AVAILABLE OTHER THAN BEING IN THIS STUDY?**

You do not have to be in this study to receive treatment for your osteoarthritis. Instead of taking part in this study, you may choose to receive treatment with other medications.

These include prescription and over the counter medications and other treatment methods such as physical therapy. The study doctor will discuss with you the risks and benefits of alternative treatments.

1. **WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?**

You may or may not receive a direct benefit from taking part in this study. However, you and future participants may still benefit from this research. The results from this study may help to develop a new treatment for you and others with osteoarthritis and other pain conditions.

1. **WHAT WILL I HAVE TO PAY FOR TAKING PART IN THIS RESEARCH STUDY?**

While you are in the study, you still need to get regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study. There will be no charge to you for your participation in this study. During the study, the study medication, study-related procedures (X-ray, ultrasounds, etc.), and study visits will be provided at no charge to you or your insurance company.

1. **WILL I BE PAID FOR TAKING PART IN THIS STUDY?**

You will not receive payment for participating in this study, but the study drug will be made available to you at no charge and you will not be required to pay for any study procedures. You will be reimbursed for any reasonable travel expenses (bus/train/taxi fares) incurred as a result of taking part in this study on production of a receipt.

1. **WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?**

Records of your participation in this study will be held confidential except as disclosure is required by law or as described in this informed consent document (under "Authorisation to Use and Disclose Protected Health Information"). The study information will be recorded in your medical notes.

All data collected will be identified by a code number and your identity will remain unknown. All information, which is collected about you that leaves the clinic, will have your name and address removed so that you cannot be recognised by it. Personal data, which may be sensitive, e.g. race, ethnic origin, health will be collected and processed electronically but only for research purposes in connection with this study.

Your study doctor is responsible for keeping a code list which makes it possible to link your assigned number to your name. This will be kept in a safe place to ensure that in case of an emergency you can be identified and contacted.

Direct access to your medical records will be required by the study team to check health related information collected for the study is correct and complete. Your medical records may also be reviewed by the regulatory authorities, ethics committees (Therapeutic Goods Administration in Australia) and auditors to check that the study is being carried out correctly. For this reason, the study team will take steps to protect your privacy and will identify you on any study-related documents only with a code.

Only the study team will have the access to the key to the code (the key enables the study team to identify individuals). If the results of this study are published or presented at meetings, you will not be identified.

You have the right to access and correct the information collected about you during the study. You should understand that by signing this consent form you are giving your permission for this to happen. Therefore, absolute confidentiality cannot be guaranteed.

A description of this clinical trial will be available on https://www.australianclinicaltrials.gov.au/. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

1. **COMPENSATION FOR INJURY**

If you are injured as a result of your participation in this trial, you may be entitled to compensation. If you suffer any injuries or complications as a result of this research project, you should contact the project team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. Your participation in this study does not affect any rights you may have under common Law.

These guidelines are available for your inspection on the Medicines Australia Website (www.medicinesaustralia.com.au) under Issues/Information – Clinical Trials – Indemnity & Compensation Guidelines. Alternatively, your study doctor can provide you with a hard-copy of the guidelines.

Your participation in this study will not affect any right you have to compensation under common law. There are two avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project: A randomised trial of colchicine for osteoarthritis of the hand.

You may be able to seek compensation through the courts.

1. **WHO SHOULD I CONTACT ABOUT MY RIGHTS OR IF I HAVE QUESTIONS?**

Before you sign this document, you should ask questions about anything that you do not understand. The study team will answer your questions before, during, and after the study. If you do not think your question was fully answered or do not understand the answer, please continue to ask until you are satisfied.

If you have any questions, concerns or complaints about this study, or how it is being run, or suffer a research-related injury, please do not hesitate to discuss your concerns with the study doctor. The phone numbers to reach the study doctor are on the first page of this document. An Independent Ethics Committee has reviewed the study and has given an approval for the study to take place. This approval does not mean that the study is safe or that you should take part in the study. You must make that decision for yourself based on the information provided in this information sheet and with consultation with both the study doctor and your own doctor.

The ethical aspects of this research project have been approved by the HREC of The Queen Elizabeth Hospital. (TQEH/LMH/MH)

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor, Professor Catherine Hill on (08) 8222 6688 or any of the following people:

 Clinical contact person

|  |  |
| --- | --- |
| Name | Carlee Ruediger |
| Position | Research Coordinator |
| Telephone | (08) 8222 7369 |

Outside of office hours and in case of an emergency you can contact your General Practitioner or local emergency department.

If you have questions regarding this study that you do not wish to discuss with your study doctor, you can contact an independent doctor that is not directly involved with the study, such as your GP

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

|  |  |
| --- | --- |
| Name | Bernadette Swart |
| Position | CALHN Research Office Manager |
| Telephone | (08) 8222 3890 |
| Email | Bernadette.swart@sa.gov.au |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | TQEH HREC |
| HREC Executive Officer | Heather O’Dea |
| Telephone | (08) 8222 6841 |
| Email | Health.CALHNResearchEthics@sa.gov.au |

Reviewing Human research Ethics Committee (TQEH/LMH/MH) approving this research and HREC Executive Officer details

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**Consent Form**

TITLE: A randomised trial of colchicine for osteoarthritis of the hand

PROTOCOL NO.: COLAH

INVESTIGATOR:Prof Catherine Hill

 The Queen Elizabeth Hospital

 28 Woodville Rd, Woodville South

**STUDY RELATED**

PHONE NUMBER(S): Carlee Ruediger

 Ph: 8222 7369

By signing below, I show that:

|  |
| --- |
| * I have read this form. The study has been explained to me in a language I understand.
 |
| * I have discussed the study with the study doctor or study nurse and have asked questions. I am satisfied with the answers.
 |
| * I have had enough time to make my decision.
* I have understood the purpose, procedures and risks involved in the study.
 |
| * I know what will happen to my blood and urine samples collected for this study.
 |
| * I know I can leave the study at any time without giving a reason.
 |
| * I know that the study doctor can ask me to stop taking part in the study at any time and he/she will tell me the reasons why.
 |
| * I know that I cannot be in another study while I am taking part in this study.
 |
| * I agree that the study doctor may tell my doctor that I am taking part in a study.
 |
|  |
|  |

**A copy of the information sheet and signed consent form will be given to you to keep.**

Participant Name Signature Date

**INVESTIGATOR/RESEARCHER OBTAINING CONSENT**

I have explained this project and the implications of participation to the participant and I believe that the consent is informed and that he/she understands the implications of participation.

Full Name of Investigator conducting Signature Date

Consent

† The investigator, or a suitably qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the consent document during the same interview when the subject signs the consent document.





