St. Vincent's SportsMed

Participant Information Sheet/Consent Form
Interventional Study

St Vincent's SportsMed/St Vincent's Private Hospital/East Sydney Private Hospital

Title	**"Measuring the effect of Hyaluronic acid (HA) on tendon healing after arthroscopic rotator cuff repair: A prospective randomized clinical trial."**
Short Title	***HA in Cuff Repair Study***
Project Sponsor	***St Vincent's SportsMed, Sydney***
Coordinating Principal Investigator/ Principal Investigator	***A/Prof Simon Tan (Principal Investigator)*** Dr Warren Kuo (Co-Investigator) Dr Ilian Eusebio (Coordinating Investigator)

Invitation

You are invited to participate in a research study investigating the healing effect of Hyaluronic acid (HA) injection in key hole shoulder surgeries. Hyaluronic acid is a substance that is naturally present in the human body. It is found in the highest concentrations in fluids in the eyes and joints. Hyaluronic acid works by acting as a cushion and lubricant in the joints and other tissues. In addition, it might affect the way the body responds to injury.

The study is being conducted by a research team from St. Vincent's SportsMed, Sydney lead by A/Prof. Simon Tan (Principal Investigator) and Dr. Warren Kuo (Co-Investigator). Dr Ilian Eusebio, the Orthopaedic Fellow will serve as the Coordinating Investigator and will correspond with you throughout the duration of the study.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

Although the clinical outcome of key hole shoulder surgery for cuff repair is generally favourable, many studies have shown that some of the repaired cuffs, especially ones with larger tears, still don't heal after surgery. In this study we examine the healing effect of HA after cuff repair. Animal studies

have demonstrated a significant positive effect of HA on tendon healing. Studies on humans have shown that HA injections relieve shoulder pain as well as conventional steroid therapy, and it may help decrease post-operative scar formation and improve outcomes after cuff repair.

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because you have a rotator cuff tear needing surgical repair through key-hole surgery.

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you decide not to participate, it will not affect the treatment you receive now or in the future. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

4. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form once you make an appointment for your surgery. You will receive a patient information form, and if you consent to participate in the study, patient-determined shoulder assessment form. The shoulder assessment form is a tool that helps us objectively determine your quality of life and function before the operation. These forms will only take you 5 minutes to fill up. You will be asked to bring these forms on the day of your surgery. On the day of surgery, you will be randomly allocated to one of the two treatment groups: the HA group or the control group. The HA group will receive the intervention, a single Hyaluronic Acid injection. The control group will receive an injection of sterile saline as placebo. The coordinating investigator will collect the patient information and consent form and the shoulder assessment form that you've filled out already at the pre-admission room. During surgery and after your cuff tendon has been repaired, a tiny surgical catheter will be placed into your shoulder at the repair site. After surgery and while you are still at recovery room, the coordinating investigator will inject either HA or sterile saline into your shoulder using the catheter placed inside your shoulder. The catheter will then be gently pulled out of your shoulder keeping the surgical dressing in place. When you come for your routine postoperative appointments, your surgeon will document your shoulder pain, range of motion, shoulder strength and functional shoulder assessment. You will also be asked to fill-out time specific shoulder assessment forms during your follow-up visits to allow us to track your progress.

When you come to see your surgeon 6 months after surgery, you'll be given a request to book magnetic resonance imaging (MRI) study for your shoulder which will be done 12 months after surgery to examine if the HA injection makes any difference regarding healing of the repaired cuff tendon.

5. 'Are there alternatives to participation?'

Your surgery will still proceed as planned if you decide not to participate in the study.

6. 'How is this study being paid for?'

The HA injections that will be used in the study will be provided by Surgical Specialties PTY Ltd free of charge. No money is paid to individual researchers.

7. 'Are there risks to me in taking part in this study?'

Medical treatments may cause adverse effects. The administration of either HA or sterile saline post-operatively is a low to negligible risk treatment modality, and has not been shown to adversely affect the outcome of the repair. The catheter will be placed prior to skin closure through a hole already created for the surgery and will be removed immediately after the injection is given. There are no perceived additional risks for you when you take part in this study, other than the risks of the surgery itself. The items listed below illustrate the potential adverse events of HA injection *WITHOUT* surgery. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these adverse effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for adverse effects. There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Shoulder joint pain	4 out of 100 (3.8%)
Joint swelling	1 out of 100 (1.1%)
Joint stiffness	1 out of 100 (0.5%)
Injection site pain (superficial)	2 out of 100 (1.6%)

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need discontinue your participation in the study. Similar to when you withdraw your consent, if your participation in the study is discontinued, personal data will no longer be collected from you, however, data that has already been collected prior to discontinuation will still be used in the study. Your study doctor will discuss the best way of managing any side effects with you.

At the 12 month post-operatively, you will be requested to have an MRI study to ascertain the completeness of the healing of your cuff. An MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the inside of the body. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. The pictures taken by the machine are called MRI scans. We will ask you to lie on a table inside the MRI scanner. The scanner will record information about your shoulder. It is very important that you keep very still during the scanning. When you lie on the table, we will make sure you are in a comfortable position so that you can keep still. The scanner is very noisy and we can give you some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you.

There are no proven long-term risks related to MRI scans as used in this research project. MRI is considered to be safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room.

8. 'What happens if I suffer adverse effects or complications as a result of the study?'

If you suffer any adverse effect or a complication as a result of this study, you should contact your Attending Surgeon (A/Prof. Simon Tan/ Dr. Warren Kuo/Dr. Ilian Eusebio) as soon as possible and they will assist you in arranging appropriate medical treatment.

9. 'Will I benefit from the study?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include enhancing the healing of cuff repair, decreasing recovery time, and improving the outcomes of patients.

10. 'Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything out of the regular fee for your surgery and routine follow up visits. There are no monetary benefits for you.

11. 'How will my confidentiality be protected?

Personal data will be collected as is standard for your consultation and surgery with the senior surgeons. If you decide to join the study, we will be recording your pre-operative condition and post-operative progress using standard forms. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Data analysis will be done using a computer software, and the file will only be accessible to the investigators. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Identifying data (name, date of birth, home address) will not be included in the data analysis, storage, and publication. Patients will instead be given a unique patient identifier. All forms and data will be stored securely at the St Vincent's SportsMed office.

12. 'What happens with the results?'

We plan to discuss/publish the results in peer-reviewed journals, presentation at conferences or other professional forums.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

13. 'What happens to my treatment when the study is finished?'

After study completion, subsequent follow-up visits may be required at the discretion of your surgeon. Regardless of your treatment allocation, the planned rehabilitation after your surgery will not differ significantly unless there is an indication to change during the course of your recover.

14. 'What should I do if I want to discuss this study further before I decide?'

If you have further inquiries regarding the study, you may contact your surgeon's rooms at (02) 8382 6969 for patients seen at St. Vincent's Sports Med or (02) 4732 4557 for patients seen at the Nepean Clinic. The coordinating investigator will get in touch with you as soon as possible.

15. 'Who should I contact if I have concerns about the conduct of this study?'

If you suffer any injuries or complications as a result of this research project, you should contact the study 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. You may contact St. Vincent's SportsMed at (02) 8382 6969 for further inquiries. Complaints regarding the conduct of the study may be reported to St Vincent's Hospital Sydney Research Office at (02) 8382 2075 or the Human Research Ethics Committee, under the National Health and Medical Research Council at 1300 064 672

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.

St. Vincent's SportsMed

CONSENT FORM

"Measuring the effect of Hyaluronic acid (HA)on tendon healing after arthroscopic rotator cuff repair: A prospective randomized clinical trial."

1. I,.....
   of.....

   agree to participate as a participant in the study described in the Participant Information Sheet set out above (or: attached to this form).
2. I acknowledge that I have read the Participant Information Sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the information sheet has been explained to me to my satisfaction.
3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the [insert names of entities].
5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
6. I understand that if I have any questions relating to my participation in this research, I may contact .....on telephone....., who will be happy to answer them.
7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Complaints may be directed to the St Vincent's Hospital Sydney Research Office: 02 8382 2075

Signature of participant Date

Signature of witness to signature Date

Signature of investigator Date

Participant will be provided with a copy of the Participant Information Sheet and this Consent Form

All parties signing the Consent Form must date their own signature

St. Vincent's SportsMed

"Measuring the effect of Hyaluronic acid (HA)on tendon healing after arthroscopic rotator cuff repair: A prospective randomized clinical trial."

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with the St. Vincent's Clinic Sydney or my medical attendants.

Signature of participant Date

Please PRINT name

The section for Revocation of Consent should be forwarded to
St. Vincent's SportsMed
St. Vincent's Clinic
Address: Suite 407, 438 Victoria street, Darlinghurst, Sydney, NSW, Australia, 2010
Telephone no: (02)8382 6969

In the event the participant decided to withdraw verbally, please give a description of the circumstances. Coordinating Investigator to provide further information here:

Coordinating Investigator to sign the withdrawal of consent form on behalf of a participant if verbal withdrawal has been given:

Name of participant Date

Signature of investigator

Participant will be provided with a copy of this Withdrawal of Consent Form