

**St. Vincent’s SportsMed**

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

## CLINICAL RESEARCH

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

# Invitation

You are invited to participate in a research study investigating the healing effect of Hyaluronic acid(HA)injection in key hole shoulder surgeries.

The study is being conducted by a research team from St. Vincent’s SportsMed/ Sydney lead by A/Prof. Simon Tan,Dr. Warren Kuo, Prof. Kim Walker and Dr. Aladen Abu-harfiel.

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.

# ‘What is the purpose of this study?’

Although the clinical outcome of key hole shoulder surgery for cuff repair including pain and ROM is generally favourable, many studies have shown that some of the cuff tendons still don’t heal after surgery Despite all the advances in surgical techniques, fixation materials and biological augmentation.

In this study we examine the healing effect of HA after cuff repair taking in consideration animal studies have demonstrated a significant positive effect of HA on tendon healing. Moreover, the efficacy and safety of HA in abdominal surgeries and in non-surgical therapy of shoulder disorders has been widely reported.

# ‘Why have I been invited to participate in this study?’

You are eligible to participate in this study because you are a candidate for an elective arthroscopic shoulder surgery and may fulfil the selection criteria for our study.

# ‘What if I don’t want to take part in this study, or if I want to withdraw later?’

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

# ‘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 a patient-determined shoulder assessment form. 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 twotreatment groups: the HA group or the control groupand the orthopaedic fellow (one of your surgeon’s assistants) will collect the consent form and the shoulder assessment form that you’ve filled out already. During surgery and after your cuff tendon has been repaired, a tiny surgical catheter will be placed safely into your shoulder at repair site. After surgery and while you are still at recovery room, the orthopaedic fellow will inject either HA or sterile water into your shoulder using the catheterplaced inside your shoulder for this reason and then he will gently pull it 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.

When you come to see your surgeon 6 months after surgery, you’ll be given a request to book an MRI imaging study for your shoulder which will be done12 months after surgery to examine if the HA injection makes any difference regarding healing of the repaired cuff tendon.

1. **‘Are there alternatives to participation?’**

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

# ‘How is this study being paid for?’

The HA injections that will be used in the study will be provided by one of the producing companies free of charge. No money is paid to individual researchers.

# ‘Are there risks to me in taking part in this study?’

Up to our knowledge and based on many studies, the administration of either HA or sterile saline is a low to negligible risk treatment modality and theoretically,it should add nothing to the normal reported risks of arthroscopic shoulder cuff repair surgery.

# ‘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) as soon as possible and they will assist you in arranging appropriate medical treatment.

# ‘Will I benefit from the study?

This study aims to further medical knowledge and may improve future treatment of arthroscopic shoulder surgery, however it may benefit you if you receive HA after surgery and our study demonstrates laterimproved tendon healing when we inject HA at repair site.

# ‘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.

# ‘How will my confidentiality be protected?

Of the people treating you, only A/Prof. Simon Tan, Dr. Warren Kuo, Prof. Kim Walker, and Dr. Aladen Abu-harfiel, will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law.

# ‘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.

# ‘What happens to my treatment when the study is finished?’

Your treatment will continue as planned in consultation with your surgeon.

# ‘What should I do if I want to discuss this study further before I decide?’

your Attending surgeon (A/Prof. Simon Tan/ Dr. Warren Kuo)will discuss the study with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact your doctor at (02)8382 6969.

# ‘Who should I contact if I have concerns about the conduct of this study?’

This study has been approved by the research committee in 3 hospitals in Sydney where the study will be conducted which are St Vincent’s Private Hospital, East Sydney Private Hospital and Nepean Private Hospital.Should you have any concerns about the study please contact the rooms of St Vincent’s Sportsmed at (02) 8382 6969. On weekend and after hours, you can contact Dr. Ilian Eusebio  at .

**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).

1. 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.
2. 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.
3. I understand that I can withdraw from the study at any time without prejudice to my relationship to the [insert names of entities].
4. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
5. 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.
6. 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 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*



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# 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:

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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*