Informed Consent Form

Study Title:

Effect of ibuprofen on postoperative opiate medication use and shoulder functional outcomes after arthroscopic rotator cuff repair

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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Effect of ibuprofen on postoperative opiate medication use and shoulder functional outcomes after arthroscopic rotator cuff repair

This is a medical research study. Your study doctor(s), Dr. C. Benjamin Ma, M.D, Dr. Brian Feeley, M.D, Dr. Alan Zhang, M.D, Dr. Christina Allen, M.D., and Dr. Drew Lansdown, M.D., from the UCSF Orthopaedic Surgery and Sports Medicine Department, will explain this study to you.

Medical research studies include only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have a rotator cuff tear and surgical treatment is being recommended.

Why is this study being done?

The purpose of this study is to compare the effects, good and/or bad of taking ibuprofen with not taking ibuprofen (ie: placebo) after arthroscopic rotator cuff repair on your pain control and shoulder results. In this study, you will get either ibuprofen or placebo to take in addition to standard prescribed opiate medications for pain control after surgery. You will not get both.

There are no financial or proprietary interests on the part of Dr. Benjamin Ma, Dr. Brian Feeley, Dr. Christina Allen, Dr. Alan Zhang, or Dr. Drew Lansdown related to this clinical study. This study is being paid for by the UCSF Department of Orthopaedic Surgery and Orthopaedic Research and Education Foundation.

How many people will take part in this study?

About 115 people will take part in this study.

What will happen if I take part in this research study?

If you agree to be in the study, you will be asked to fill out some surveys during your office visit. These include basic questions about you, your health history, your normal activities and your shoulder injury. This information will be copied and entered into our secure database.

You will take ibuprofen or placebo three times every day (meaning every 8 hours) for two weeks.

You will randomly be assigned to one of two groups on the day of your surgery. Randomization means that you will be put into a group by chance. A computer program will place you in one of the groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group. Neither you nor your doctors will know which group you have been assigned to. Only the research coordinator will know with treatment group

you are in and this will be documented in our secured database.

- If you are in group 1, you will receive ibuprofen to take postoperatively for pain control. This is the current practice at UCSF. Detailed instructions on how the medication should be taken will be provided. You will be given a two week supply.
- If you are in group 2, you will receive placebo to take postoperatively for pain control. Placebo is defined as "an inactive substance." Detailed instructions on how the medication should be taken will be provided. You will be give a two week supply.

Both groups will be given a pain log booklet to take home on the day of surgery. You will use this booklet daily to record when you take pain medications and your associated pain level rated on a scale of 0-10 (0 = no pain, 10 = worst pain ever). You will turn this booklet in at your first postoperative visit for analysis. You will also be asked to bring in your pain medication bottles including the one you were assignment and the opiate medication.

You may not take additional acetaminophen (Tylenol) or anti-inflammatory medications during the first two weeks of the study.

At your standard 6-week, 3-month, 6-month, 1-year, and 2-year postoperative check-ups, you will again be asked to fill out surveys. At the 1-year postoperative visit, you will also get an ultrasound study of your shoulder to evaluate the rotator cuff repair. The ultrasound study will take about 15-30 minutes. There is no exposure to radiation with ultrasound.

The office visits will be part of the standard care for your shoulder injury. The only things added by the study are the surveys you will be asked to fill out and the ultrasound study of your shoulder.

How long will I be in the study?

This is a two-year study. You will be asked to take ibuprofen or placebo for two weeks after surgery. You will see us at regular intervals of 6 weeks, 3 months, 6 months, 1 year, and 2 years after surgery, as do all of our patients who undergo arthroscopic rotator cuff repair.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. They will tell you how to stop your participation safely.

The study doctors, Benjamin Ma, M.D., Brian Feeley, M.D., Dr. Alan Zhang, M.D., Dr. Christina Allen, M.D., and Dr. Drew Lansdown, M.D., may stop you from taking part in this study at any time if they believe it is in your best interest, if you do not follow the study rules or meet the study criteria, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help

lessen side effects. Many side effects go away soon after you stop taking ibuprofen. In some cases, side effects can be serious, long lasting, or may never go away

You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and side effects related to the ibuprofen include those which are:

Likely

- Abdominal discomfort
- Nausea
- Constipation

Less Likely

- Rash
- Tinnitus or ringing in the ears
- Bruising

Rare but serious

- Stomach ulcer
- GI bleed
- Kidney dysfunction or kidney injury
- Anaphylaxis (a severe and life-threatening allergic reaction)

Randomization risks: You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

Placebo risks: If you are in the group that receives placebo, your postoperative pain will go without the active (study) treatment with ibuprofen for 2 weeks after your surgery.

Unknown Risks: The study treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, this study will help doctors learn more about the effect of ibuprofen on postoperative pain control and surgery outcomes, and it is hoped that this information will help in the treatment of future patients with similar rotator cuff tears that require surgery.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting no postoperative treatment
- Getting standard treatment for your condition without being in a study.
- Getting a different experimental treatment/taking part in another study.
- Getting what is current practice at UCSF: postoperative ibuprofen.

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The University of California
- Orthopaedic Research and Education Foundation
- The US Food and Drug Administration (FDA)

What are the costs of taking part in this study?

Your insurance will be billed for the costs of the surgical procedure, all visits, treatments, and tests described above, just as would be done if you did not take part in the study, with the exception of the study medication (ibuprofen or placebo) and the ultrasound study at 1 year follow up visit, which will be paid for by the study sponsor, the UCSF Orthopaedic Surgery and Sports Medicine Department.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. C. Benjamin Ma, M.D, Dr. Brian Feeley, M.D, Dr. Alan Zhang, M.D, Dr. Christina Allen, M.D, Dr. Drew Lansdown, M.D., if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 415-353-7896.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctors at: Dr. C. Benjamin Ma (415-353-7866), Dr. Brian Feeley (415-353-7586), Dr. Alan Zhang (415-353-7596), Dr. Christina Allen (415-885-3832), or Dr. Drew Lansdown (415-514-6120).

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

CONSENT

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you per HIPAA.

You have been given copies of this consent form, the HIPAA research authorization form, and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____	_____
Date	Participant's Signature for Consent
_____	_____
Date	Person Obtaining Consent