UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE A RESEARCH SUBJECT

"A CLINICAL TRIAL OF POSTOPERATIVE LIDOCAINE INFUSION ON COGNITION AND OPIOID CONSUMPTION FOLLOWING MAJOR SPINE SURGERY"

A. PURPOSE AND BACKGROUND

Dr. Marc Buren from the Department of Anesthesia & Perioperative Care is conducting a study to learn whether the addition of a medication called lidocaine to patients after surgery makes any difference on the amount of pain experienced, pain medication requirement, and recovery of brain function after surgery.

Lidocaine, a non-narcotic drug, has been increasingly used as part of anesthesia pain regimens to minimize the amount of opioid pain medications that patients require during and after surgery. Lidocaine is not currently approved by the FDA specifically for the treatment of postoperative pain. However, it has been extensively used during surgeries as part of the anesthetic "cocktail", and is part of many enhanced recovery after surgery protocols that are designed to minimize pain after surgery and speed recovery.

Because of its ability in reducing pain, lidocaine is being studied for its potential in the surgical setting for pain reduction after surgery, decrease of narcotic use and its associated side effects, and promotion of the recovery of mental function such as memory and orientation.

You are being asked to participate in this study because you are 60 years of age or older and undergoing major spine surgery.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. Pain management: Before surgery, with the approval by your treating surgeons and anesthesiologists, you will be randomly assigned to one of two types of pain management strategies after surgery. This means that you will have a 50/50 chance of being in either group and that neither the doctor nor you will make the choice of which group you will be in.

- If you are in Group 1: You will receive a drug called lidocaine that will be given continuously through an intravenous catheter for 48 hours following surgery. The dose will be 1.33mg/kg/hr. You will also receive standard (usual) pain medications after surgery. Standard pain medications include narcotic pain medications taken by mouth or administered through the IV (intravenous) catheter, commonly called PCA (patient controlled analgesia). The type of oral pain medications will be decided by your surgeon, and the pain medication given via the PCA is typically hydromorphone (Dilaudid).

- If you are in Group 2: You will receive standard (usual) pain medications after surgery. Standard pain medications include narcotic pain medications taken by mouth or administered through the IV (intravenous) catheter, commonly called PCA (patient controlled analgesia). The type of oral pain medications will be decided by your surgeon, and the pain medication given via the PCA is typically hydromorphone (Dilaudid). In addition to standard pain medications, you will receive a placebo infusion (normal saline) after surgery for 48 hours.

2. Medical records review: Before and after surgery, your medical chart will be reviewed to collect information such as demographics, length of hospital stay, and pain scores.

3**. Thinking and memory:** Before and after surgery your mental function will be evaluated by the investigators using several tasks that test your memory and learning, verbal and language skills, attention, concentration, and perception. These tasks will take about 15 minutes. The purpose of the tasks is to help us determine whether your attention and memory, etc., change after surgery and whether or not a lidocaine infusion improves recovery of these tasks after surgery. These tasks will be performed before surgery, daily for the first week after surgery, at discharge, and at one and three months after surgery by telephone or in person.

If you stay in the hospital longer than one week after surgery, a weekly evaluation will be done until discharge.

4. Study withdrawal: You may be withdrawn from the study without your consent if the researchers believe it is in your best interest.

5. Time involved in participation: Participation in the study will usually take a total of about 1-6 hours over a period of about 1-2 months. Depending on the length of the inpatient stay, and time to administer the cognitive tests and pain assessments, the time commitment could be more or less.

C. RISKS/DISCOMFORTS

1. Randomization: You will be assigned to a pain treatment type by chance. The type of treatment you receive may prove to be less effective or to have more side effects than the other treatment type.

2. Risk of Lidocaine: the reported side effects of lidocaine in treatment of surgical pain include sedation, dizziness, a metallic taste, and ringing in the ears. However, in studies of lidocaine used for the treatment of postoperative pain, the above side effects are rare.

3. Other risks: Procedures such as the measurement of your mental function only present a small inconvenience and/or may be tiring, but you are free to decline to answer any questions.

4. Confidentiality: Participation in research may involve a loss of privacy; however, your records will be handled as confidentially as possible. The researchers will not use your name or any information that might identify you in reports or publications that may result from this study. If you agree to participate, all information will be kept confidential and in locked files belonging to the researchers.

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 Institutional Review Board at 415- 476-1814.

D. BENEFITS

There may be no direct benefit to you from participating in this study. While doctors hope the addition of lidocaine will be more effective and have fewer side effects than the standard (usual) treatment, there is no proof of this yet, and the lidocaine infusion could lead to an increase in side effects. If you are in the group that receives lidocaine and it proves to treat pain more effectively and with fewer side effects than placebo, you may benefit from participating in the study, but this cannot be guaranteed.

E. ALTERNATIVES

If you choose not to participate in this study, you will receive the pain treatment type chosen by your anesthesiologist and surgeon with your consent, and this might include the use of lidocaine.

F. COSTS

The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

G. PAYMENT

You will not be paid for participating in this study.

H. QUESTIONS

This study has been explained to you by Dr. Buren or _____ (the person who signed below) and your questions were answered. If you have any other questions about the study, you may call Dr. Buren at (415) 514-3771.

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 Institutional Review Board at 415-476-1814.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

I. CONSENT

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

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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, you should sign below, and you will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

_____	_____
Date	Participant's Signature

_____	_____
Date	Person Obtaining Consent