

A randomized, double-blinded, controlled study of the efficacy of quinacrine in the treatment of sporadic Creutzfeldt-Jakob disease

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This is a research study to determine if the medicine quinacrine (used previously to treat malaria) improves the survival of patients with sporadic Creutzfeldt-Jakob disease (sCJD).

This study is voluntary. If you decide to take part in this study, you can stop at any time.

This study is sponsored by the National Institutes of Health and plans to enroll approximately 60 patients over three years.

This is a brief summary of what happens in this study:

1. Prior to study enrollment, you will undergo a comprehensive review of your medical history and records. You, your caregiver(s), and/or physician(s) will be asked questions about your current and past medical conditions, demographics, laboratory results, medications, family's medical history and social history (travel, hobbies, education, etc...) in order to determine the likelihood of a diagnosis of sCJD.
2. If, after a review of your medical history, medical records and family medical history, it is felt that you could have sCJD, you will come to UCSF for additional evaluation and possible study enrollment.
3. At UCSF
 - You will undergo several diagnostic procedures or tests, some of which may be clinically necessary to confirm your diagnosis of sCJD and others that, although clinically useful, are primarily for research purposes. These include, but are not limited to:
 - i. MRI (a scan that takes a picture of your brain)
 - ii. Electroencephalogram (EEG; measures brain waves)
 - iii. Lumbar puncture (spinal tap)
 - iv. Blood tests
 - v. Urine tests
 - You and your caregivers will be asked questions about your medical history, the course of your illness, and your family medical history.
 - You will have a brief medical examination, a videotaped neurological exam, and neurocognitive testing.

- If you are determined to have sCJD by our study team and you fulfill other study criteria, you will be randomized to either quinacrine or placebo (a sugar pill). You will have 50:50 chance of being placed on quinacrine or placebo.
- You will start the study drug (quinacrine or placebo) as an inpatient at UCSF.
- You will be discharged home and asked to return to UCSF, if possible, at 2 and 12 months.
- At 2 months, all patients will be offered quinacrine.
- You will be followed on at least a monthly basis with blood toxicity monitoring and telephone follow-up.

The **risks** of this study are:

1. Possible worsening or no change in condition. We do not know if quinacrine will help patients with sCJD. Quinacrine may worsen, or have no effect on patients with, sCJD.
2. Possible side-effects from the quinacrine, such as liver, heart, blood, and behavioral problems.
3. Discomfort, headache and infection (unlikely) from the lumbar puncture.
4. Discomfort from lying still in the MRI machine or for the EEG.
5. Fatigue in undergoing neurological and neuropsychological testing.
6. Disclosure of personal medical information will result in a loss of privacy, however, records will be kept as confidential as possible.

The **benefits** of this study are:

1. Quinacrine may improve survival of patients with sCJD.
2. We may learn if future sCJD patients will benefit from quinacrine.
3. Your participation may improve the medical community's understanding of your condition.

For more information about this study, please contact:

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