

PREQUEL

PARTICIPATING INSTITUTIONS

- **Baylor College of Medicine**
Houston, TX
William Ondo, MD ~ Christine Hunter, RN, CCRC
(713) 798-3951
- **Colorado Neurological Institute**
Englewood, CO
Vicki Segro ~ Diane Erickson, RN
(303) 762-6674
- **Emory University School of Medicine**
Atlanta, GA
Randi Jones, PhD ~ Cathy Wood-Siverio, MS
(404) 728-4782
- **Hennepin County Medical Center**
Minneapolis, MN
Martha Nance, MD ~ Dawn Radtke, RN, CCRC
(612) 873-2943
- **Indiana University**
Indianapolis, IN
Joanne Wojcieszek, MD ~ Jo Belden, LPN, CCRC
(317) 278-0868
- **John Hopkins University**
Baltimore, MD
Russell Margolis, MD ~ Nadine Yoritomo, RN
(410) 614-9254
- **University of California ~ Davis**
Sacramento, CA
Vicki Wheelock, MD ~ Terry Tempkin, RNC MSN
(916) 734-6278
- **University of Iowa**
Iowa City, IA
Leigh Beglinger, PhD ~ Nancy Hale, BS, RN
(319) 353-4537
- **University of Rochester**
Rochester, NY
Fredrick Marshall MD ~ Amy Chesire, LCSW-R, MSG
(585) 341-7519
- **Washington University**
St. Louis, MO
Susan Criswell, MD ~ Melissa Ammel
(314) 747-3470

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PREQUEL

Primary Leadership Committee

CHRISTOPHER ROSS, MD, PHD
PRINCIPAL INVESTIGATOR

KEVIN BIGLAN, MD, MPH
CO-PRINCIPAL INVESTIGATOR

MERIT CUDKOWICZ, MD
BERNARD RAVINA, MD, MSCE
MICHAEL MCDERMOTT, PHD
JANE PAULSEN, PHD
FLINT BEAL, MD
IRA SHOULSON, MD
STEVEN HERSCH, MD, PHD
ROBERT FERRANTE, PHD, MSC
RAY DORSEY, MD, MBA
TIM O'NEIL, MD
SUZANNE DOGGETT, PC
LISA de BLIECK, MPA, CCRC*
ELAINE JULIAN-BAROS, BS, CCRC*
SHARI KINEL, JD*

*EX-OFFICIO

H·S·G
Huntington Study Group

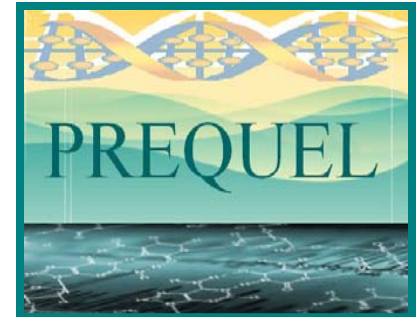
For more information
please visit the HSG website at :

www.huntington-study-group.org

A clinical research study of
PRE-manifest Huntington's
disease of coenzyme Q10
(UbiquionE) Leading to
preventive trials

~ **PREQUEL** ~

**A MULTI-CENTER
DOUBLE-BLIND
RANDOMIZED CLINICAL
STUDY**



*SUPPORTED BY A
GRANT FROM
THE NATIONAL
INSTITUTE
OF
NEUROLOGICAL
DISORDERS
AND STROKE
(NINDS)*

PREQUEL *Study Information...*

What is the PREQUEL Study?

The purpose of this study is to assess the safety of coenzyme Q₁₀ (CoQ) in healthy people who have tested positive for the HD gene expansion and are “pre-manifest” (meaning would not be diagnosed with HD based on a physical exam). CoQ is a nutritional supplement that has been found to be well tolerated and is available over the counter. The goal of this study is to determine whether high dosages of CoQ are well tolerated and to assess the usefulness of certain markers of HD in the blood which may help measure the rate of disease progression or effects of medication.

The PREQUEL study is not designed to see whether or not CoQ is an effective treatment for HD, but that it is safe and well tolerated over the course of this 20 week study in pre-manifest individuals.



Who Can Participate?

MAIN INCLUSION CRITERIA:

- Participants must be 18 years of age or older.
- Participants must have been previously tested gene positive for the CAG expansion in the HD gene and are pre-manifest based on a physical exam.
- Concomitant medications are permitted with the exception of CoQ and Creatine > 5g/day.

MAIN EXCLUSION CRITERIA:

- A history of intolerance to CoQ.
- CoQ use within 60 days prior to randomization.
- Substance abuse within one year.
- Pregnant, breastfeeding or lack of reliable contraception in women of childbearing age.

What will occur if you choose to participate in the PREQUEL study?

A screening visit to verify eligibility will occur.

You will be randomly assigned to receive either 600, 1200 or 2400 mg/day of CoQ(capsules).

The study visits include a general physical and neurological exam focused on HD, including tests to evaluate movement, mood, and mental functioning. Blood and urine samples will also be obtained in order to assess your general health.



How can you benefit from participating in PREQUEL?

You may or may not benefit from participation in this study. You will receive additional evaluations by a study doctor who specializes in Huntington’s disease. You will also contribute to our knowledge about Huntington’s disease prior to the development of symptoms and about the safety and tolerability of CoQ in people with the Huntington’s Disease gene.

Are there risks involved?

Participants may experience mild symptoms such as heartburn, headache, feeling of tiredness and bowel symptoms. Also, there is no information available regarding the effect of CoQ in pregnant or nursing women. There is also a risk of the occurrence of previously unknown side effects.

How can you find out more information about the PREQUEL study?

Please contact the nearest participating institution listed in this brochure or visit the following Huntington Study Group website at:

www.huntington-study-group.org

What is the Huntington Study Group (HSG)?

The Huntington Study Group (HSG) is a non-profit group of clinical investigators from medical centers in the United States, Canada, Europe and Australia, experienced in the care of Huntington patients and dedicated to clinical research of Huntington disease (HD). The HSG was formed in 1993, prompted by the recognition that clinical research in HD required the participation of large numbers of research participants under the cooperative effort of skilled and experienced research physicians.

What has the HSG accomplished?

The HSG has carried out cooperative therapeutic research since 1993, beginning with the development of the Unified Huntington’s Disease Rating Scale (UHDRS) and the Natural History database. Since then we have carried out several multi-center clinical research studies to examine the short-term symptomatic and potential disease-modifying effects of experimental interventions in Huntington disease as well as large observational studies.

The HSG has partnered with pharmaceutical companies, private foundations, the National Institutes of Health (NIH) and the FDA Orphan Drug Products Division in developing and conducting these trials.

Since our inception, we have published all of our research projects in internationally recognized peer-reviewed journals in an effort to make public all of our research progress in HD. Our publication list currently includes journal articles, abstracts, reports, releases and position papers.

