

Who is eligible to participate in DOMINO?

The main eligibility requirements include:

- ❖ Age 18 years or older
- ❖ Clinical features of HD *and* a confirmatory family history of HD; and/or genetically confirmed HD
- ❖ Independently walking and fully self-sufficient in activities of daily living (eating, dressing, bathing)
- ❖ Able to take medication (capsules) by mouth

Are there risks to me as a participant in DOMINO?

The most commonly reported side effects include nausea, vomiting, diarrhea, dry mouth, dizziness, skin rash, discoloration of skin, sensitivity to sun, allergy, swelling of tongue and mouth, difficulty swallowing, yeast infection in the mouth, vaginal swelling or dryness. Because skin sensitivity to sun could be a side effect with minocycline, you should wear protective clothing (long pants and long sleeved shirts) and sun block lotion when you are outside.

Some people experience changes in white blood cell counts and liver function while on minocycline. Routine monitoring will be provided during the study.

If you are on blood thinner, you should inform the study doctor as minocycline may interfere with its action.

These risks are further explained in the consent form, and the research investigator or coordinator can also answer any questions.

What study procedures will occur if I am willing to participate in DOMINO?

If you would like to participate, you will have screening and baseline visits to determine your eligibility. If eligible, you will begin to take the study drug and be evaluated every three months for a period of eighteen months. The research center will also contact you by telephone two times during the study to see how you are feeling.

At the beginning of the study you will be randomly assigned (like the roll of the dice) to receive either the active drug (minocycline) or a look-alike drug with no active ingredients (placebo). You will have a 3 out of 4 chance of receiving minocycline.

Study procedures will include a general physical and neurologic exam focused on Huntington's disease, including evaluations of mood and thinking. Blood samples will be taken to assess general health. A blood sample will be

taken at the beginning of the study and sent to a research lab to confirm if you carry the abnormal HD gene. If you are a woman of child-bearing potential you will be tested for pregnancy at every visit.

How would I benefit by participating in DOMINO?

You may or may not receive benefit from participating in the DOMINO study. However, you will receive additional evaluations of your condition by a Huntington's disease specialist. You may also contribute to the growing knowledge about Huntington's disease.

How do I find out more information about participating in the DOMINO Study?

If you are interested in learning more about this study, please contact the Huntington Study Group at the toll free number:

1-(800) 487-7671

OR

www.Huntington-Study-Group.org



DOMINO Participating Sites:
Albany Medical College; Albany NY
Colorado Neurological Institute;
Englewood, CO
Columbia University; New York, NY
Massachusetts General Hospital;
Boston, MA
University of Alabama at Birmingham;
Birmingham, AL
University of British Columbia;
Vancouver, BC
University of Florida; Gainesville, FL
University of Maryland; Baltimore,
MD
University of Rochester; Rochester,
NY
University of South Florida; Tampa,
FL
University of Texas Medical Center;
Galveston, TX
Washington University School of
Medicine; St. Louis, MO

What is the Huntington Study Group?

The **Huntington Study Group (HSG)** is an international association of more than 200 clinical investigators, coordinators, scientists and staff from 55 participating hospitals and universities in North America, Europe and Australia.

The HSG is supported by the Huntington's Disease Society of America (New York, NY), the Hereditary Disease Foundation (Santa Monica, CA), HP Therapeutics, Inc. (New York, NY), and the Huntington Society of Canada (Cambridge, Ontario).

Formed in 1993, the HSG strives to advance knowledge about the cause, process and clinical impact of HD in order to develop and test promising therapeutic interventions.

For more information about the HSG, please visit our website at:
www.Huntington-Study-Group.org

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DOMINO Steering Committee

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DOMINO

A Multi-Center, **Double-Blind**, Pilot Study of **Minocycline** in Huntington's Disease (HD)



Enrollment Complete



conducted by the
Huntington Study Group (HSG) and
funded by a grant from the Food and
Drug Administration (FDA)

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What is a clinical trial?

A clinical trial is a study to evaluate promising experimental treatments. They are designed to learn if new medications are safe, tolerable and effective. A clinical trial differs from an observational study in which people are examined over time without receiving any experimental drugs or treatments.

What is the DOMINO study?

The DOMINO study is a clinical trial being conducted at approximately 12 research centers in North America (US and Canada) for people ages 18 and older who have symptoms of, a positive family history of and/or a positive genetic test for Huntington's disease (HD). Each research center will enroll approximately 8-10 people with HD. The study will last approximately 18 months.

The main purpose of this study is to determine the effect of minocycline on the progression of Huntington's disease and whether further study of the use of the drug in Huntington's patients is warranted.