

Total Eye Care

Colleyville, Texas

Consent Form for Participation in a Pre-Clinical Research Study

TITLE: Vascular Fundus Changes Observed in Patients with High Probability of CCSVI (Chronic Cerebrospinal Venous Insufficiency), Including Patients with Multiple Sclerosis and/or Ehlers-Danlos Syndrome

INVESTIGATORS: Drs. Richard and Diana Driscoll, Therapeutic Optometrists, Glaucoma Specialists, Connective Tissue Disorder Specialists; Dr. Clair Francomano, MD, Director, Adult Genetics Program Harvey Institute for Human Genetics, geneticist, researcher, speaker, author

This is an important form. Please read it carefully. It tells you what you need to know about this research study. If you agree to take part in this study, you need to sign this form. Your signature means that you have been told about the study and the potential risks. Your signature on this form also means that you want to take part in this study.

Why is this research study being done?

This study is being done to get a better understanding of the changes in the arteries and veins of the fundi (the back of the eye) of patients who are prone to CCSVI (chronic cerebrospinal vascular insufficiency). This study will include patients with suspected and/or confirmed multiple sclerosis, Ehlers-Danlos Syndrome and “normal” patients.

How many people will take part in this research study?

The plan is to include 30 age-matched “normal” control patients and 30 patients with suspected and/or confirmed multiple sclerosis and/or Ehlers-Danlos Syndrome, for a total of 60 study participants.

What will happen in this research study?

The study will take place at the office of Total Eye Care located in Colleyville, Texas and will take approximately 1.5 hours.

When you arrive at the office, we will confirm your identity, and collect a copy of your paperwork (you will complete this prior to attending the study) and your doctor’s diagnosis of multiple sclerosis and/or Ehlers-Danlos Syndrome, OR we will confirm your list of symptoms suspecting one of these conditions. **You do not need a firm diagnosis or a letter from your doctor in order to participate in this study.**

We will then check your flexibility with the Beighton scale of flexibility.

Next, we may ask you to remove your contact lenses, should you be wearing any, and we will take very high resolution photographs of the back of your eye using the **optomap**[®]. This is not painful or invasive in any way. You will be seated (a wheelchair is fine) and

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the technician will guide your head gently so that you are in proper position to obtain the best photographic image. This should take less than 30 seconds. You will need to be able to bend forward slightly and turn your head slightly for the photo.

We will check the pressures of your eyes with a Goldmann tonometry. This involves the use of alcaine (a numbing drop) and a drop of fluorescein on your eyes. Again, you will be asked to lean forward slightly to place your chin on the instrument. This test is completely painless and takes less than a minute to perform.

We will also obtain an autorefractor reading (an estimate of your prescription).

None of these tests are invasive, nor do they require dilation of the eyes. You will have the opportunity to meet with one or both of the doctors for counseling concerning your case, and referrals to specialists in the field if you so desire.

May I leave the study if I desire to do so?

Taking part in this research study is your decision. You may decide to stop at any time. Additionally, the doctors may stop you from taking part in this study at any time if it is in your best interest, or if the study is discontinued for any reason.

Is there any cost to participating in the study?

You will be exposed to no out-of-pocket costs. If you have medical insurance that will cover the cost of testing, we will submit for payment and accept assignment. If your insurance does not cover this testing, we will perform this at no cost to you. There is no remuneration to you for participating in the study, but we will provide for you, at no cost, a copy of our research results.

Will my identity be protected?

As is true with any medical record, your test results will remain strictly confidential. Your profile and results will be identified by a number, rather than your name for evaluation (the doctor evaluating the results will not know who you are and will not know if you fall into the multiple sclerosis, Ehlers-Danlos, or “normal” category). If you allow your results to be used for further research, your results may be stored indefinitely and confidentially at Total Eye Care.

There is a very small chance that some commercial value may result from the use of your sample. If that would happen you will not be offered a share in any profits.

Are there any risks to participation?

All medical information available indicates that there is no risk to pregnant women or women who are breast feeding (or to their babies). If you are allergic to fluorescein or any of the “-caine” drugs (alcaine, novocaine, etc.), please inform the doctor.

If you are uncomfortable in the position needed to obtain the test results, please inform the technician or doctor. This may (or may not) be something we can work around. No side effects from testing are anticipated.

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A copy of this form will be placed in your medical record.

I have had an opportunity to have my questions answered. I have been given a copy of this form. I agree to take part in this research study.

Date

Printed Name of Participant

Signature of Participant

Date

Printed Name of Individual Obtaining Consent

Signature of Individual Obtaining Consent