As a Study Participant:

If you agree to participate in the C-TRACT study, a member of the team will:

- Review your medical records,
- Review your medical records, health history, and medications.
 Perform a physical exam including measurements of your leg and venous ulcer (if present).
 Collect a small amount of blood to check your general health
- to check your general health and for future research (with your permission). Perform imaging to assess
- venous blood flow.
- Ask you to complete questionnaires about your PTS symptoms and quality of life.

Treatment Assignment:

Patients will be randomly assigned (like the flip of a coin) to high quality PTS care or high-quality PTS care plus endovascular therapy (EVT).

Visit Frequency:

If assigned to high quality PTS care plus EVT, you will return in approximately 1 week for stent placement.

Patients assigned to both groups will return for visits at: 2 Months, 4 Months, and 6 Months.

Costs to Participate:

Because some treatments and procedures may be part of your regular clinical care, your insurance may be billed. The study team will discuss potential costs with you.

Participants will receive \$100 after completion of each follow up visit and free compression stockings at entry and 6 months.

To Learn More, please contact:

The C-TRACT Study is funded by the National Heart, Lung and Blood Institute (NHLBI) within the National Institutes of Health (NIH)

https://bloodclotstudy.wustl.edu 1-866-974-CLOT (2568) CTRACT@wustl.edu

Collaborating Institutions: McMaster University – OCOG Massachusetts General Hospital -VasCore St. Luke's Mid America Heart Institute (MAHI) **C-TRACT Coordinating Center:**



Defining the future of **Post-Thrombotic** Syndrome (PTS) Treatment



C-IK4

CHRONIC VENOUS THROMBOSIS

a Call <u>1-866-974-CLOT</u> (2568)

email: CTRACT@wustl.edu



DVT: Deep Vein Thrombosis

Post-Thrombotic Syndrome (PTS): Treatment and Prevention

How a DVT leads to PTS



- 1. Valves in the leg veins help blood flow in the right direction.
- 2. The blood clot and inflammation (the body's response to the clot) damage leg vein valves.
- 3. The damaged valve becomes leaky and allows pressure to build up in the leg veins.
- 4. The leg becomes heavy, swollen and painful, and may develop skin change or open sores.

Used with permission of creator, Dr. Susan Khan 2010.

Can PTS be Treated?

Yes, but some available treatments don't always work, and others have not yet been fully evaluated.

Current conservative therapies include:

- Elastic Compression Stockings (ECS);
- External compression devices that are placed on the leg to improve circulation;
- Supervised exercise programs;
- "Venoactive" medications to reduce venous pressure or in inflammation.

Some patients with more severe symptoms do not respond to these therapies or only partially improve. Some physicians use catheter-based endovascular therapy (EVT) procedures such as stent placement (small metal mesh tubes to open the vein).



Current PTS Research

The C-TRACT study is designed to help us understand whether (EVT) procedures such as stent placement might reduce the severity of PTS symptoms and improve quality of life.

Findings from the study may change how doctors care for patients with PTS.

Volunteer for PTS Research

The C-TRACT study is seeking 250 volunteers with moderate to severe PTS to participate.

- **1.** Are you \geq **18** years of age or older?
- 2. Have you been diagnosed with a blood clot in your leg in the past (more than 3 months ago)?
- 3. Do you now have leg heaviness, fatigue, swelling, aching, or pain?

If you answered all three questions "YES", then you might be a perfect fit for the C-TRACT Study.

To learn more, go to: https://bloodclotstudy.wustl.edu

A DVT is the formation of a blood clot within a deep vein most commonly in the leg. Between 350,000 and 600,000 people develop DVT each

year in the US. DVT

affects men and women at all ages.

People who develop DVT often have one or more of the following risk factors:

- Recent major trauma or surgery
- Cancer
- Limited mobility due to medical illness, paralysis or other condition
- Pregnancy
- Hormonal treatments (e.g. birth control pills)
- Medical disorders of the blood clotting system (often inherited).

Potential Long-Term Effects of DVT

DVT survivors often experience long-term pain, swelling, heaviness, fatigue, skin changes, and/or open sores on the legs - a complication called **Post-Thrombotic Syndrome (PTS)**.

Although blood thinning medications are important treatment to reduce the risk of recurrent DVT and to prevent pulmonary embolism (a clot breaking o and moving to the lung arteries), PTS develops frequently despite the use of these medications. Approximately 25-50% of patients with a first episode of DVT go on to develop PTS.