RESET·HA

RESET THE WAY YOU MANAGE JOINT PAIN.

A CLINICAL RESEARCH STUDY
FOR HEMOPHILIC ARTHROPATHY


A POTENTIAL
NEW DIRECTION FOR
FINDING RELIEF
RESET·HA

WE'RE LOOKING TO RESET TREATMENT OPTIONS FOR HA

The RESET-HA Study is a clinical research study for people who experience joint pain due to hemophilia.

The study is evaluating an oral non-opioid investigational drug designed to be taken once a day to see if it may potentially help relieve joint pain and improve physical function in patients with hemophilic arthropathy (HA).

YOU MAY BE ELIGIBLE TO PARTICIPATE IN THIS CLINICAL RESEARCH STUDY IF YOU:

- Are 18 to 75 years of age (inclusive)
- Have been diagnosed with hemophilia A or B for at least six months
- Have chronic pain in one or more joints
- Do not take opioid medication more than four days a week

If you are interested in taking part in the **RESET-HA** Study, please review the information in this brochure and speak with a member of the study staff.

WHAT IS HEMOPHILIC ARTHROPATHY?

HA occurs when people with hemophilia experience bleeding in their joints (such as their knees, ankles, elbows, hips, and shoulders). This can cause the joints to become swollen and painful.

Over time, repeated bleeding into the joints can lead to chronic joint pain and permanent joint damage.

What makes managing hemophilic arthropathy pain difficult is that many common pain relievers can affect how your blood clots and aggravate bleeding. Opioid-based medications are also used to help provide pain relief; however, their use may lead to unwanted side effects and dependence.

Currently, there are no approved treatment options designed to specifically address HA pain. That is why we're conducting the RESET-HA Study.

OUR GOAL:

EFFECTIVE PAIN RELIEF. REDUCED RISK OF GI BLEEDING. LESS OPIOID USE.

Traditionally, HA pain management often involves the use of nonselective NSAIDs and opioids. However, long-term use of these medications can result in increased risk of GI bleeding (NSAIDs) and dependency (opioids).

Researchers in the **RESET-HA** Study are evaluating an investigational drug – a cyclooxygenase-2 (COX-2) selective NSAID – which is designed to potentially help reduce pain caused by HA and improve physical function in a way that is different from other medications.

The sponsor of the clinical research study (Tremeau Pharmaceuticals) believes that the investigational drug may provide effective pain relief for those with HA:

1. Without affecting blood clotting;
2. With a lower risk of GI bleeding compared to currently available NSAIDs; and
3. Without the risk of dependency that can occur with use of opioids.

STUDY OVERVIEW

ALL ELIGIBLE STUDY PARTICIPANTS WILL RECEIVE AT NO COST:

- A comprehensive assessment of your health
- Study-related care and monitoring
- Study drugs (investigational drug or placebo), rescue medication, and gastroprotective medication (if applicable)

Study participation is expected to last up to 68 weeks and includes 11 study visits. Participation is divided into three parts: a Screening Period, a Placebo-controlled Study Treatment Period, and a Study Treatment Extension Period.

SCREENING PERIOD
(UP TO FOUR WEEKS)

You will be asked to read and sign an Informed Consent Form, which contains information about the **RESET-HA** Study, including detailed information about the study, potential risks and benefits of participating, and your rights as a study participant. During this time, the study doctor will review your medical history and conduct several health-related tests, assessments, and procedures to determine if you are eligible to participate.

PLACEBO-CONTROLLED STUDY TREATMENT PERIOD

PART I (12 WEEKS)

You will be randomly assigned (like flipping a coin) to receive the investigational drug or placebo (an inactive substance). This will be your assigned study drug, which you will take every day in Part I. You will also attend five study visits to monitor your health and assess the safety and effectiveness of the investigational drug.

STUDY TREATMENT EXTENSION PERIOD

PART II (52 WEEKS)

During this period, all study participants will receive the investigational drug. You will attend five study visits to continue to monitor your health and assess the safety and effectiveness of the investigational drug. You will also be contacted by the study staff two weeks after you complete the study to ask how you are feeling.

WHAT IS EXPECTED OF STUDY PARTICIPANTS?

All study participants will be expected to take their assigned study drug as directed, attend all scheduled study visits, and follow the instructions of the study doctor and study staff. Study participants will also take part in regularly scheduled study-related tests, assessments, and procedures to monitor their health and the effects (if any) of the investigational drug.

In addition, all study participants will be required to regularly (daily, weekly, and monthly) enter information about their symptoms of HA in an electronic diary (e-diary).

Reimbursement for travel-related study expenses may also be available. Speak to a member of the study staff for additional information.

RESET-HA

Let's Discuss Your Options

To learn more about the **RESET-HA** Study and to see if it may be an option for you, please speak with a member of the study staff or visit our website.

resetHAstudy.com

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