Purpose of the TARGET BP I Study

This study investigates the effectiveness and safety of the Peregrine System™ Kit in treating high blood pressure (hypertension).

The study will enroll patients with uncontrolled hypertension despite taking 2-5 anti-hypertension medications.

Patients who qualify for the study will have an opportunity to review a detailed informed consent form with all the study information. It will describe why this study is being performed and what it involves.

The study involves a randomization to one of two groups (like flipping a coin). One group will be randomized to the "Treatment arm". This group will be treated with the investigational product called the Peregrine System Kit. The second group will be randomized to the "Control arm" and will not be treated with the Peregrine System Kit. Both groups will remain on a stable regimen of antihypertensive medications during the trial.

Participation in the Study

Patients may be eligible for the TARGET BP I Clinical Trial if they:

- Are between the ages of 18 and 80
- Are currently taking 2-5 anti-hypertensive drugs
- Have high blood pressure (upper value greater than 150mmHg) despite taking anti-hypertensive drugs

Your study doctor will help to decide whether you are eligible to take part in this study.

FOR MORE INFORMATION, CONTACT:

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The Peregrine System Kit is an investigational product not currently approved in the United States. Its use is limited to investigational use in clinical trials.

Study sponsored by:

ABLATIVE SOLUTIONS

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For more information, you can also visit
www.TargetBP1.com

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IRB Approved at the
Protocol Level
Jun 01, 2021

TARGET BP I
CLINICAL TRIAL

PATIENT BROCHURE

MA0009 v2.0, 23APR2021

CAUTION: The Peregrine System Kit is an investigational product that is currently being studied to evaluate safety and effectiveness when used in the treatment of patients with uncontrolled hypertension and is limited to investigation use in clinical trials.

Facts about Hypertension

Hypertension is a condition in which the force of blood flowing through a person's blood vessels is consistently too high. Over time, this puts stress on the arteries, the heart and the kidneys, which increases the risk of stroke, kidney disease and heart attack.[1,2]

Treating High Blood Pressure

Standard approaches in treating high blood pressure such as diet, exercise, and prescription drugs can be effective for some people. However, despite these treatments, less than half of people with hypertension are able to effectively manage their high blood pressure.[3,4]

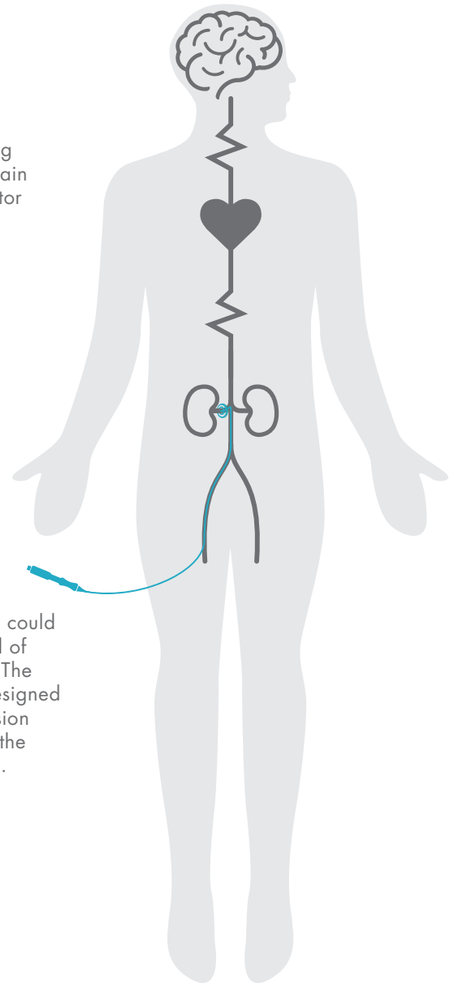
Investigational Product Targeting Renal Nerves

For these individuals not able to manage their blood pressure, with current approaches, an investigational product is being studied for the treatment of hypertension using a procedure called renal denervation.

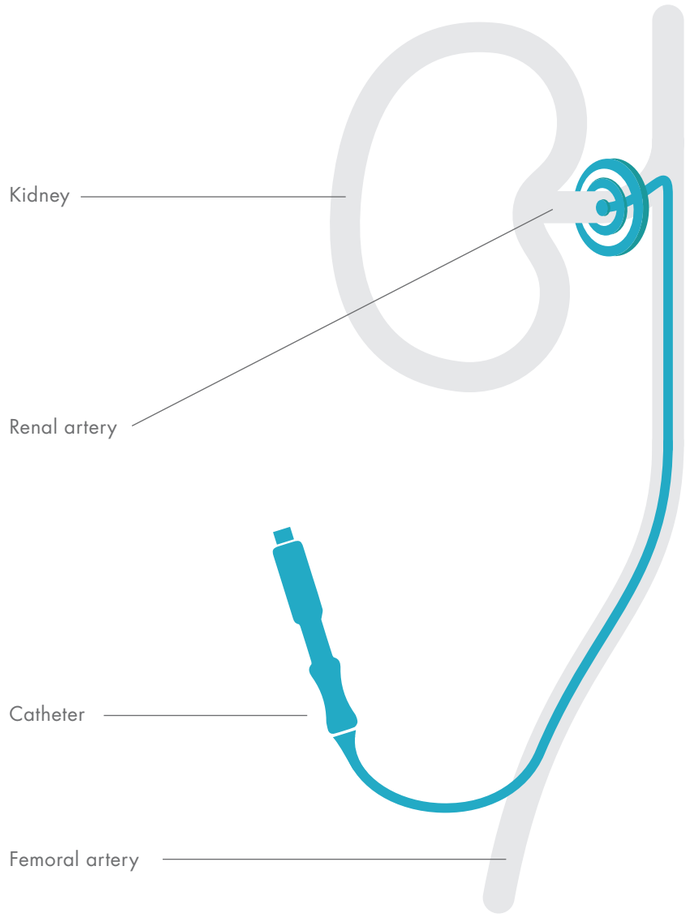
Nerves that run from the kidney to the brain transmit signals that help control blood pressure, but overactive signaling can contribute to raising blood pressure. The TARGET BP I study is evaluating a catheter-based procedure designed to deactivate these overactive nerves with a targeted infusion of dehydrated alcohol.

The purpose of this study is to evaluate the safety and effectiveness of renal denervation while you are still on your blood pressure medications.

Overactive nerve signaling from the kidneys to the brain can be a contributing factor in high blood pressure.



Deactivating these nerves could potentially aid in the goal of lowering blood pressure. The Peregrine System Kit is designed to deliver a targeted infusion of dehydrated alcohol to the nerves to deactivate them.



What is the Study Procedure?

This minimally-invasive procedure will be performed under mild sedation. Your study doctor will help explain the procedure and office visits required for regular follow up, approximately 40 months (about 3 years).

The Peregrine Catheter will be inserted through a small incision in the groin and guided up to the renal arteries using angiography (like an X-ray). The system will deliver a small amount (0.6 mL/artery) of dehydrated alcohol to the region just outside the artery where the sympathetic nerves are located, to deactivate these nerves.

During the study period, you will be asked to see your doctor at regular time points for clinical assessments, which could include blood pressure measurements, blood and urine samples, and a physical examination.

For more details, please consult with the study doctor.

1 World Health Organization, Q&A on Hypertension, Updated Sept. 2015 (information accessed 07Feb2019) www.who.int/features/qa/82/en/

2 https://www.nhlbi.nih.gov/health-topics/high-blood-pressure

3 CDC, https://www.cdc.gov/bloodpressure

4 Williams et al, 2018 ESC/ESH Guidelines for the management of arterial hypertension, European Heart Journal (2018), 1–98 doi:10.1093/eurheartj/ehy339

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