What Is Primary Hypothyroidism?

The thyroid is a small, butterfly-shaped gland in the front of the neck that makes thyroid hormones (T4 and T3) that control the way the body uses energy. With hypothyroidism, or underactive thyroid, the thyroid gland does not produce enough thyroid hormones, which can lead to fatigue, weight gain, cold sensitivity, dry skin, and hair loss as well as neurological symptoms that can affect memory and mood.

What Is the AVANTI Study?

The purpose of the AVANTI Study is to evaluate if an investigational medicine is safe and effective in the treatment of primary hypothyroidism. The study will compare the effect of the investigational medicine on primary hypothyroidism and its safety with Synthetic Drug T4 (Levothyroxine).

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The AVANTI Study

Step Up and Be Part of Primary Hypothyroidism Research

Who Can Participate in the AVANTI Study?

Adults may qualify to participate in the AVANTI Study if at the Screening Visit they meet the following criteria:
Are 18 – 75 years of age
Have been diagnosed with primary hypothyroidism for at least 12 months
Have been on continuous thyroid replacement therapy with an FDA approved dose of synthetic T4 for at least 12 months, and at a stable dose for at least 3 months
Have a BMI between 18 and 40
Meet additional study criteria

What Does Participation in the AVANTI Study Involve?

Adults with primary hypothyroidism often need to adjust their medication and/or care plan as thyroid hormone levels change. For this reason, participants in the AVANTI Study may benefit from the close monitoring of their thyroid hormone values.

During study visits, the study team may ask questions, collect vital signs, and perform certain lab tests to ensure the health and safety of each participant, and gather essential information on the impact of study treatment.

How Long Does the AVANTI Study Last?

Participation in this study may last up to approximately 90 weeks and includes 3 treatment periods plus a screening and follow-up period:

- **Screening period:** During this time, the study team will confirm eligibility and determine if the study may be a good option for the potential participant.
- **Run-in period:** All study participants will start with the run-in period, using an investigational medicine as their only source of thyroid replacement therapy for 19 – 29 weeks.
- **Double-blind treatment period:** Participants who are eligible for the double-blind treatment period will be randomly assigned (like the flip of a coin) to receive either synthetic T4 medication or the investigational medicine for 26 weeks.
- **Open-label extension period (OLE):** Those who complete the 26-week double-blind treatment period will be given the opportunity to enter an additional 26-week open-label extension (OLE) period during which all participants will receive only the investigational medicine.
- **Follow-up:** A follow-up phone call will take place 35 days after the lost dose of study drug.

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What Can Participants Expect from the AVANTI Study?

- Adults who meet study criteria and choose to participate will receive:
- The study medication (either the investigational treatment or synthetic T4) and all study-related care at no cost
- Care and close monitoring from doctors and staff with expertise in hypothyroidism
- The option to join the open-label extension (OLE) after completing the double-blind period, in which all participants will receive the investigational medicine
- Reimbursement for certain expenses related to study participation

To ensure patients can make an informed decision about this study, each will go through a process called informed consent. This will provide details about participation, including the potential risks and benefits, and address any questions related to the study. Potential participants who chose to move forward with the AVANTI Study can opt to leave the study at any time, for any reason.

Ask your doctor if the AVANTI Study may be right for you or talk to the staff at the site listed on the back of this brochure.