What are clinical trials?

Clinical trials help scientists and doctors explore whether a therapy is safe and whether it works. Before a doctor can prescribe a new therapy, it must go through several phases of clinical research:

Phase 1: First trial of the therapy in people

Phase 2: Trial of the therapy in people with the condition the therapy is for

Phase 3: Trial confirming how well the therapy works

Phase 4: More research after the therapy is approved

The SBT777101-02 clinical trial is a Phase 1 trial.

Clinical trials rely on volunteers. Remember that taking part in the trial is your choice. Know that the rules and ethics that doctors must follow to practice medicine also apply to clinical trials.

Relief of Hidradenitis Suppurativa symptoms may be on the horizon

Sonoma Biotherapeutics is developing an investigational therapy for people with Hidradenitis Suppurativa (HS). Learn more about the SBT777101-02 clinical trial.

For more information about the SBT777101-02 trial, contact:

SONOMA BIOTHERAPEUTICS

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Who can join the clinical trial?

You may be eligible to join the clinical trial if you meet the following criteria*:

- Between 18–70 years old
- Current diagnosis of clinically active moderate to severe HS
- Presence of at least 1 skin lesion accessible for biopsy
- Body mass index (BMI) ≤ 50 kg/m²

*Other criteria apply.

What is the purpose of the clinical trial?

Researchers in the SBT777101-02 clinical trial are studying a possible cell therapy for people with HS who do not benefit from standard therapies.

What is cell therapy?

The goal of cell therapy is to use the participants' own cells to improve their condition. In many cases, the original cells taken from the participant are 'engineered' so that the cells can be directed to manage the disease. For example, cells can be directed to fight cancer cells or directed to improve the immune system.

What is the trial cell therapy?

- The trial cell therapy is called SBT777101 and is made from the participants' own cells.
- The trial cell therapy is designed to work by adding new DNA (instructions that tell cells how to do their job) to certain immune cells, which may help reduce inflammation and restore immune balance in people with HS.
- The trial cell therapy is investigational, which means it can only be used in clinical trials. It has not been approved by any regulatory authorities as an effective therapy for HS.

How is the trial cell therapy made?

1. The participant's blood is drawn into a machine that separates certain immune cells from other cells in the blood.

2. Scientists genetically modify the immune cells.

3. Cells are left to grow and multiply for 2 weeks.

4. Scientists check the cells for quality.

5. Participant receives an infusion of the trial cell therapy.

What can participants expect?

If you decide to join, you can expect to participate in the following:

- **Screening (about 4 weeks)**
  - Complete screening assessments to find out if you qualify for the trial.
  - Screening assessments include, but are not limited to, vital signs, physical exam, heart test (ECG), blood and urine tests, and optional skin biopsy.

- **SBT77101 cell therapy preparation (about 6 weeks, but up to 6 months is allowed)**
  - Before the cell therapy is given, you will complete the following:
    - Apheresis (blood is drawn into an approved apheresis machine to separate the cells used for the SBT777101 cell therapy).
    - Pre-trial health assessments to confirm that it is safe to receive the SBT777101 cell therapy.

- **SBT777101 cell therapy and trial health assessments (about 11 months)**
  - If you qualify, you will receive the SBT777101 cell therapy as a one-time IV infusion on Day 1 of the trial.
    - You will be asked to stay overnight at the trial clinic so the trial doctor and staff can monitor your health closely.
  - Receive trial health assessments that include, but are not limited to, vital signs, blood tests, questionnaires, urine tests, heart tests, physical exams, and skin biopsy.

- **Long-term follow-up (up to 15 years)**
  - Continue to the long-term follow-up period for up to 15 years. You will receive more information from the trial staff.