NOVARTIS

The effects and safety of HSY244 for people with atrial fibrillation

Thank you!

Thank you to the participants who took part in the clinical trial for atrial fibrillation, also called AFib. Every participant helped the researchers learn more about the trial drug **HSY244**.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public.

We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CHSY244X2201
Drug studied: HSY244
Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?

The purpose of this trial was to learn about the effects of the trial drug HSY244 on heart rhythm in people with atrial fibrillation. This trial also helped researchers learn about the safety of HSY244.

Atrial fibrillation, also called **AFib,** is an abnormal heart rhythm, which means the heart beats too slow, too fast, or in an irregular way. AFib can cause serious problems, such as blood clots and stroke.

HSY244 is a trial drug that researchers think could return an abnormal heart rhythm to normal in people with AFib.

The main questions this trial was designed to answer:

- Did participants who received HSY244 have their heart rhythm return to normal?
- What adverse events did the participants have during this trial?
  An adverse event is any sign or symptom that the participants have during a trial.

How long was this trial?

The trial began in November 2020 and ended in January 2023. It was planned for the participants to be in the trial for about a month. This included the time from starting treatment to the last time trial staff checked in with the participants. Participants began this trial on different dates.

In January 2023, the sponsor stopped the trial. The decision to end this trial early was not related to the safety of the trial drug.

Who was in this trial?

13 participants with AFib were in this trial – 12 men and 1 woman. The participants were 50 to 78 years old. Their average age was 60.

12 participants reported their race as White, and 1 participant reported their race as Other.

Every participant in this trial was taking certain blood thinners, which is medicine to lower the chance of blood clots.

This trial took place in these countries:

- **Germany** | 9 participants
- **The United States** | 4 participants

What trial treatments did the participants receive?

Participants were randomly assigned to receive one of these treatments:

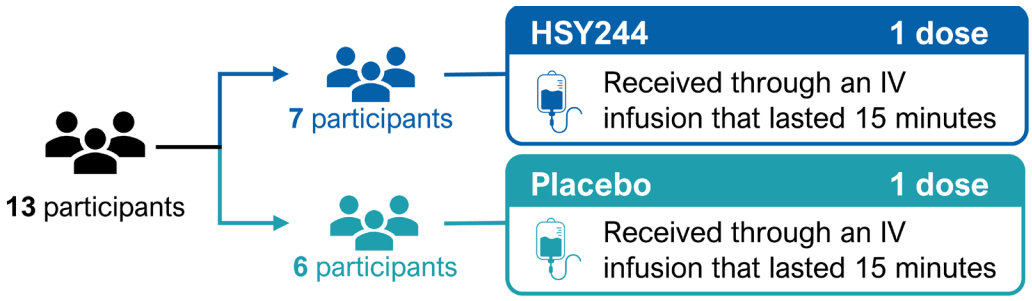
- **HSY244** – 150 milligrams (mg)
- **Placebo** – looks like the trial drug but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

The participants received their assigned treatment one time through a needle in a vein, which is called an intravenous (IV) infusion that lasted about 15 minutes. A computer program was used to randomly assign the treatments. This helped make sure the researchers compared the results as fairly as possible.

Participants could continue taking certain medicines for AFib.

The participants, researchers, and most trial staff did not know what treatment each participant received. Some trials are done this way because knowing what treatment participants receive can influence the results. Not knowing what treatment participants receive helps make sure the results are looked at fairly.

The graphic below shows how many participants were assigned each treatment.



What were the main results of this trial?

Did participants who received HSY244 have their heart rhythm return to normal?

None of the participants who received HSY244 or the placebo had their heart rhythm return to normal.

To find this out, the participants had a **continuous electrocardiogram (ECG)** to measure their heart rhythm.

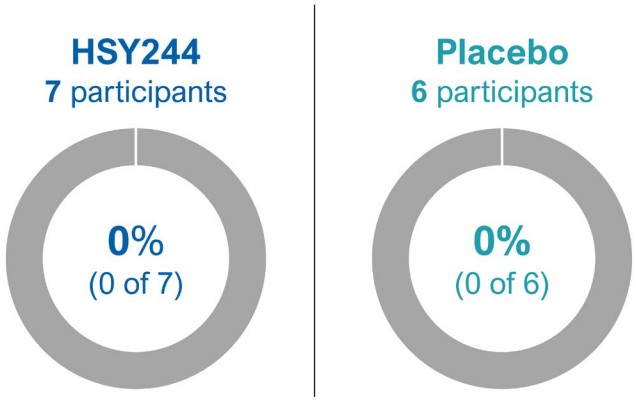
The researchers counted how many participants had their heart rhythm return to normal for at least 1 minute during the 90 minutes after starting their IV infusion.

None of the participants had their heart rhythm return to normal for at least 1 minute.

What is a continuous ECG?

An ECG records the heart's electrical signals with each heartbeat. A continuous ECG records non-stop using a small, wearable device. The device records for a set period of time, such as about 24 hours.

Number of participants whose heart rhythm returned to normal



What other results were learned?

How much and how fast did HSY244 get into the blood?

The researchers found that the total amount of HSY244 in the blood was similar to what was expected based on a past trial. HSY244 reached its peak level in the blood at the end of the IV infusion, which happened at about 15 minutes.

To find this out, the trial staff took many blood samples from each participant during the trial. This let the researchers learn how much HSY244 was in the participants' blood over time.

What adverse events did the participants have during this trial?

Trial doctors keep track of **all** adverse events that happen in trials, even if they think the adverse events are **not** related to the trial treatments.

Many trials are needed to know if a drug or treatment causes an adverse event.

An adverse event is:

- Any **sign or symptom** that the participants have during a trial.
- Considered **serious** when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death.

Adverse events **may** or **may not** be caused by treatments in the trial.

The adverse events in this section include any that happened during treatment and up to a month after completing treatment.

The researchers concluded there were no safety concerns for HSY244. A similar number of adverse events happened between the treatment groups. None of the participants left the trial because of an adverse event.

How many participants had adverse events?

The table below shows the number of participants who had adverse events during the trial.

	HSY244 7 participants	**Placebo** 6 participants
Participants who had at least 1 adverse event	**86%** 6 of 7	**83%** 5 of 6
Participants who had at least 1 serious adverse event	**14%** 1 of 7	**0%** 0 of 6
Participants who left the trial due to an adverse event	**0%** 0 of 7	**0%** 0 of 6
Participants who died during the trial	**0%** 0 of 7	**0%** 0 of 6

What were the serious adverse events?

One participant who received **HSY244** had 1 serious adverse event:

- **AFib that came back** and caused a longer hospital stay | atrial fibrillation

No other participants had serious adverse events, including no deaths.

What were the other adverse events?

The table below shows the adverse events that happened in **2 or more** participants. Additional adverse events happened to fewer participants.

	HSY244 7 participants	Placebo 6 participants
Joint pain Arthralgia	**14%** 1 of 7	**33%** 2 of 6
AFib that came back Atrial fibrillation	**14%** 1 of 7	**17%** 1 of 6
Blood pressure went up Blood pressure increased	**29%** 2 of 7	**0%** 0 of 6
Low potassium levels Hypokalemia	**14%** 1 of 7	**17%** 1 of 6

What was learned from this trial?

This trial helped researchers learn about the effects and safety of HSY244 in people with AFib. None of the participants who received HSY244 or the placebo had their heart rhythm return to normal. The researchers found no safety concerns for HSY244 in this trial.

The researchers also learned that the total amount of HSY244 in the blood was similar to what they expected based on a past trial.

This was one of many trials a drug goes through. This type of trial helped researchers learn about the safety of a trial drug in a small number of participants.

Where can I learn more about this and future trials?

To learn more about this trial, go to any of these websites:

- **novctrd.com** – search using the study number **CHSY244X2201**
- **clinicaltrials.gov** – search using the number **NCT04582409**
- **clinicaltrialsregister.eu/ctr-search** – search using the number **2020-004327-17**

At this time, no other trials are planned for HSY244 in AFib.

Full trial title:

A randomized, placebo-controlled, investigator- and participant-blinded study to evaluate the efficacy, safety, tolerability, and pharmacokinetics of HSY244 in participants with atrial fibrillation

? If you participated in the trial and have **questions** about the results, please speak with the trial doctors or staff at your trial site. Always talk to a doctor before making any changes to your health care.

NOVARTIS

Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

1-888-669-6682 (USA)

+41-61-324 1111 (EU)

www.novartisclinicaltrials.com