

Clinical Trial Results

Drug Studied: JZP-110, also known as solriamfetol

A trial to learn how solriamfetol worked and how safe it was in people with excessive daytime sleepiness caused by narcolepsy



Thank you!

Thank you to the people who took part in this clinical trial to study JZP-110, also known as solriamfetol or Sunosi®. The participants in this and other clinical trials helped researchers learn more about how solriamfetol works in people who have excessive daytime sleepiness caused by narcolepsy.

Jazz Pharmaceuticals sponsored this trial and thinks it is important to share the results with the trial participants and the general public.

If you participated in the trial and have questions about the results, please speak to someone at your trial site, or talk to your doctor.

It is important to note that this summary only shows the results of a single trial. Other trials could have different results. Researchers and health authorities look at the results of many trials to determine which drugs work and how safe they are. It takes many participants in multiple trials around the world to help answer these questions.

What has happened since the trial ended?

The participants were in this trial for about 14 to 18 weeks, but the entire trial took about 1 year and 9 months to finish. The trial started in May 2015 and ended in February 2017.

Jazz Pharmaceuticals reviewed the data when the trial ended and created a report of the results. This is a summary of that report.

You can find more information about this trial in the websites listed at the end of this summary.

Why was the research needed?

Narcolepsy is a chronic sleep disorder. One of the major symptoms of narcolepsy is feeling very sleepy during the day, a condition known as **excessive daytime sleepiness**. People with narcolepsy may fall asleep when they are supposed to be awake. Their excessive daytime sleepiness makes it hard for them to do many of the things they need to do every day.

Some people with narcolepsy experience episodes of sudden muscle weakness, also called **cataplexy**, which can make it difficult to talk or move.

There is no cure for narcolepsy, but there are medications and healthy lifestyle habits that can help manage daytime symptoms.

Solriamfetol is a drug that is thought to affect 2 chemicals in the brain that help keep people awake during the day. Researchers have studied it as a possible treatment for people who have excessive daytime sleepiness caused by narcolepsy.

The main questions the researchers wanted to answer in this trial were:

- Did solriamfetol help the participants stay awake during the day?
- Did solriamfetol help the participants feel less sleepy during the day?
- What medical problems did the participants have during the trial?

Who took part in the trial?

To answer these questions, the researchers asked for the help of 82 men and 154 women with excessive daytime sleepiness caused by narcolepsy.

There were 236 participants in this trial from 57 trial sites. There were:

- 172 participants in the United States
- 20 participants in Canada
- 20 participants in Germany
- 14 participants in France
- 6 participants in Finland
- 4 participants in Italy

Everyone in this trial was 18 to 70 years old when they joined.

What kind of trial was this?

This was a Phase 3 trial. In a Phase 3 trial, a drug is usually tested in a large number of participants with a specific disease or condition. Drugs tested in Phase 3 trials have already been studied in smaller trials. Phase 3 trial participants help researchers learn more about how a drug works and how safe it is.

This was also a “double-blind” trial. This means that none of the participants, doctors, or other staff knew during the trial which treatment each participant was taking. Some trials are done this way because knowing what treatment each participant is taking can affect the results. When the trial ended, the sponsor found out which treatment each participant took so they could report the trial results.

The participants in this trial took one of the following treatments every morning:

- Solriamfetol 75 milligrams
- Solriamfetol 150 milligrams
- Solriamfetol 300 milligrams
- A **placebo**

A placebo looks like the trial drug but does not have any real medicine in it. When participants take a placebo, they follow the same steps in a trial as someone who takes the trial medicine. The only difference is whether or not the participant gets the trial drug. This helps researchers better understand the actual effects of the drug.

The researchers used a computer program to randomly choose the treatment each participant would take.

What happened during the trial?

Before treatment started, people who wanted to join the trial met with a trial doctor. The doctors made sure that everyone who joined the trial had narcolepsy and excessive daytime sleepiness that could not be explained by other common causes, such as too little sleep at night, a work schedule that interfered with regular nighttime sleep, or a medical problem besides narcolepsy. They also gave the participants a full check-up to make sure they were healthy enough to join the trial. This took up to 1 month.

During the trial, the participants took their assigned treatment every morning for 12 weeks. They visited the trial site 5 more times. During these visits, the trial staff checked the participants’ health by measuring their vital signs – such as temperature and blood pressure – and looking at their heart activity with a test called an “electrocardiogram”. The participants:

- Told the trial staff how they were feeling and what medications they were taking
- Completed questionnaires
- Gave blood and urine samples

During 3 of these visits, the participants stayed overnight at the trial site so the trial doctors could study their nighttime sleep and daytime sleepiness.

The nighttime sleep study, which is called “polysomnography”, measured brain function, eye movements, muscle activity, heart function, and blood oxygen levels during sleep.

Daytime sleepiness was measured with the **Maintenance of Wakefulness Test**, which measured each participant’s ability to stay awake during the day in a dark and quiet room. This test helps researchers understand how well someone functions and stays alert during quiet times of the day when they are less active.

Throughout the trial, the trial staff also contacted the participants by phone to ask how they were feeling and what medications they were taking. If a participant had cataplexy, they also kept a diary throughout the trial to keep a record of their cataplexy attacks.

After treatment ended, the participants visited the trial site 1 more time as part of this study. This happened about 2 weeks after they finished treatment.

The figure below shows how the trial was done.



What were the results of the trial?

This is a summary of the overall results of the trial. Results for each participant may have been different and are not in this summary. You can find more information about this trial – including other questions the researchers wanted to answer – in the websites listed at the end of this summary.

Researchers look at the results of many trials to decide which treatments work best and are safest. Other trials could have different results.

Did solriamfetol help the participants stay awake during the day?

To answer this question, the trial doctors looked at how long the participants were able to stay awake during the **Maintenance of Wakefulness Test (MWT)**. This is called the **MWT sleep latency**.

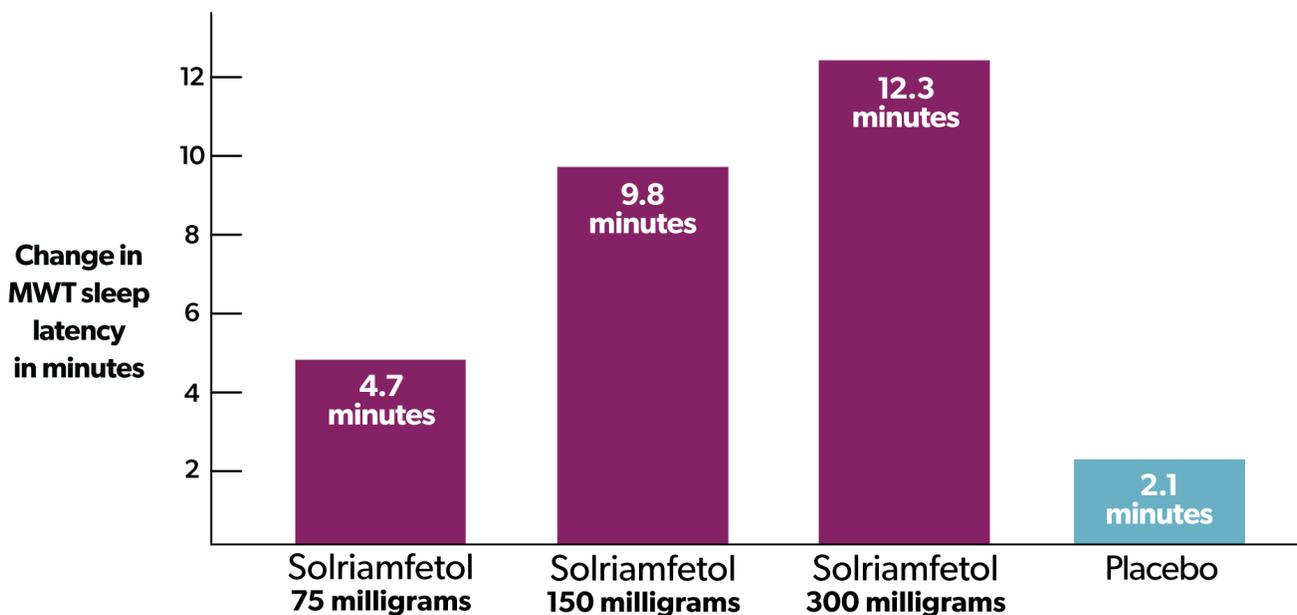
The doctors measured the participants' MWT sleep latency from 1 to 9 hours after they took their assigned treatment. Then they looked at how MWT sleep latency changed after 12 weeks for the participants who took solriamfetol compared with the participants who took a placebo.

If a participant's MWT sleep latency increased over time, it means that they were able to stay awake longer during the test.

After 12 weeks of treatment, the average amount of time that participants could stay awake increased more for participants who took 150 milligrams or 300 milligrams of solriamfetol each morning than for participants who took a placebo. But the difference between the group that took the lowest dose of solriamfetol (75 milligrams) and the group that took a placebo was too small for the researchers to know whether this difference was caused by the trial drug.

The figure below shows the change in MWT sleep latency after 12 weeks in each of the treatment groups.

Change in Maintenance of Wakefulness Test (MWT) sleep latency after 12 weeks of treatment



An increase in MWT sleep latency means participants were able to stay awake longer during the Maintenance of Wakefulness Test

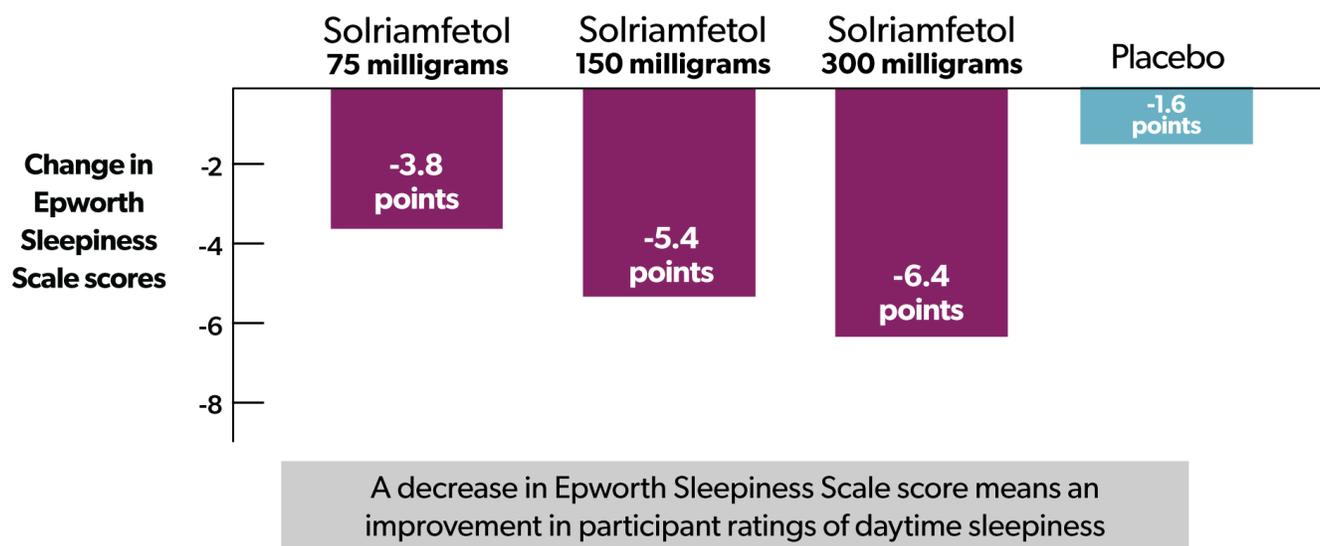
Did solriamfetol help the participants feel less sleepy during the day?

To answer this question, the trial doctors looked at how the participants responded to a questionnaire called the **Epworth Sleepiness Scale**. This questionnaire asked the participants to rate how likely they were to fall asleep in different situations.

Higher scores mean more daytime sleepiness.

After 12 weeks of treatment, average daytime sleepiness scores dropped more for the participants who took solriamfetol each morning than for the participants who took a placebo.

Change in Epworth Sleepiness Scale scores after 12 weeks of treatment



What were the other results of the trial?

The participants also completed a questionnaire that asked them to rate how they thought their overall condition had changed from the start of treatment to the end of treatment. The researchers looked at questionnaire responses from 231 of the 236 participants.

After 12 weeks, more participants who took solriamfetol each morning rated their condition as improved compared with the participants who took a placebo:

- 40 of 59 participants (68%) who took solriamfetol 75 milligrams reported improvement
- 43 of 55 participants (78%) who took solriamfetol 150 milligrams reported improvement
- 50 of 59 participants (85%) who took solriamfetol 300 milligrams reported improvement
- 23 of 58 participants (40%) who took a placebo reported improvement

What medical problems did the participants have during the trial?

This section is a summary of the medical problems the participants had during this trial. These medical problems are called **adverse events**. An adverse event is considered “serious” when it is life threatening, causes lasting problems, or requires hospital care.

A lot of research is needed to know whether a treatment causes a medical problem. So, when new drugs are being studied, researchers keep track of all of the medical problems that participants have during a trial.

The websites listed at the end of this summary may have more information about the medical problems that happened in this trial.

What serious adverse events happened during the trial?

One participant who took solriamfetol 150 milligrams had 2 serious adverse events. This participant had chest pain that was not caused by a heart problem, also called non-cardiac chest pain, and anxiety. The trial doctors thought these serious adverse events were not related to treatment with solriamfetol.

There were no deaths during the trial.

How many participants had any adverse events?

The table below shows how many participants in each group had adverse events and how many participants stopped their trial treatment because of adverse events.

	Solriamfetol 75 milligrams Out of 59 participants	Solriamfetol 150 milligrams Out of 59 participants	Solriamfetol 300 milligrams Out of 59 participants	Placebo Out of 59 participants
How many participants had at least 1 adverse event?	34 participants (57.6% of the group)	47 participants (79.7% of the group)	40 participants (67.8% of the group)	27 participants (45.8% of the group)
How many participants stopped taking their trial treatment because of an adverse event?	1 participant (1.7% of the group)	3 participants (5.1% of the group)	5 participants (8.5% of the group)	1 participant (1.7% of the group)

What adverse events did the participants have?

The table below shows the most common adverse events that happened in at least 10% of the participants in any treatment group. There were other adverse events, but they happened in fewer participants.

The most common adverse events in this trial

	Solriamfetol 75 milligrams Out of 59 participants	Solriamfetol 150 milligrams Out of 59 participants	Solriamfetol 300 milligrams Out of 59 participants	Placebo Out of 59 participants
Headache	6 participants (10.2%)	14 participants (23.7%)	18 participants (30.5%)	3 participants (5.1%)
Nausea	3 participants (5.1%)	6 participants (10.2%)	10 participants (16.9%)	1 participant (1.7%)
Loss of appetite	5 participants (8.5%)	5 participants (8.5%)	9 participants (15.3%)	1 participant (1.7%)
Common cold	5 participants (8.5%)	8 participants (13.6%)	3 participants (5.1%)	3 participants (5.1%)
Dry mouth	3 participants (5.1%)	4 participants (6.8%)	6 participants (10.2%)	2 participants (3.4%)

How has this trial helped?

The results of this trial helped the researchers learn more about how solriamfetol works in people with excessive daytime sleepiness caused by narcolepsy. Clinical trials like this are important to help researchers understand which treatments work best and are safest for patients.

Researchers and health authorities look at the results of many trials to understand how a drug works. This summary only shows the main results from this trial. Other trials might provide different results. If you have questions about these results, please speak with the doctor or staff at your trial site, or talk to your doctor.

Clinical trials with solriamfetol are ongoing, and more trials are planned.

Where can I learn more about this trial?

You can find more information about this trial on the websites listed below. If a report of the results is available, it can also be found there.

- <http://www.clinicaltrialsregister.eu> – On this website, click “Home and Search”. Then type **2014-005487-15** in the search box and click “Search”.
- <http://www.clinicaltrials.gov> – On this website, type **NCT02348593** into one of the search boxes and click “Search”.

Trial title: A Twelve-week, Double-blind, Placebo-controlled, Randomized, Parallel-group, Multicenter Study of the Safety and Efficacy of JZP-110 [(R)-2-amino-3-phenylpropylcarbamate hydrochloride] in the Treatment of Excessive Sleepiness in Subjects with Narcolepsy

Protocol number: 14-002

You can find more information about solriamfetol here:

- https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211230s000lbl.pdf

Sponsor: Jazz Pharmaceuticals • jazzpharma@medcomsol.com

Thank you!

Jazz Pharmaceuticals would like to thank the people who participated in this clinical trial. Clinical trial participants help researchers and health authorities find answers to important health questions and discover new treatments.



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