Clinical Trial Results

Drug Studied: TV-44749

Safety, Tolerability, and Pharmacokinetic Study of TV-44749 in Chinese Patients with Schizophrenia

This is a summary of the results of a clinical trial. Teva sponsored this trial and thinks it is important to share the results with the trial participants and the general public.

This summary only shows the results of one trial. Other trials could have different results. Researchers and health authorities look at the results of many trials together to determine whether a treatment works and to understand its safety profile. It takes many participants in many trials to help answer these questions.

Full trial title: A Phase 1, Single Dose, Parallel Cohort Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of TV-44749, Olanzapine for Extended-Release Injectable Suspension for Subcutaneous Use, in Chinese Patients with Schizophrenia

Trial phase: Phase 1

Protocol number: TV44749-PK-10188

Why was this trial done?

Schizophrenia is a serious mental illness. Most people with schizophrenia need to take medicine for a long time to help control their symptoms, prevent the illness from coming back, and make it easier for them to live their daily lives.

It can be challenging to treat schizophrenia because some people forget or may choose not to take their medicine regularly. This can cause their symptoms to return and may lead to more hospital visits. If medicines can be given as shots that last a long time, it can help people take their treatment as needed.

TV-44749 includes olanzapine (a medicine used to treat schizophrenia) and a formulation method so the medicine can be given as a shot under the skin (subcutaneously) once a month.

The main purpose of this trial was to evaluate the safety and tolerability of TV-44749 in Chinese participants with schizophrenia.

Who took part?

To be in this study, participants had to be:

- between the ages of 18-64 years old
- of Chinese origin
- diagnosed with schizophrenia
- clinically stable, on oral olanzapine and not on other antipsychotic treatment

There were 24 participants who joined the trial. There were 15 males and 9 females. The average age was 38.9 years.

The trial took place in China.

What happened during the trial?

This trial consisted of:

Period 1:

- Screening period to determine if participants were eligible to enter the trial (up to 40 days)
- Once daily oral olanzapine treatment period (7 days)
- Washout period with no treatment to allow the oral olanzapine to clear out of the body (7 days)

Period 2:

- TV-44749 single dose treatment period (approximately 28 days)
- Follow-up period including an end of study visit (approximately 14 days)

Participants were assigned to 1 of 3 groups:

Cohort	Oral olanzapine (Period 1)	TV-44749 single dose (Period 2)
1	10mg/day	318 mg
2	15mg/day	425 mg
3	20 mg/day	531 mg

This was an open-label study which means that the participants and trial doctors knew which trial treatment the participants were assigned to.

Participants were expected to take part in the trial for approximately 13 weeks. The entire trial lasted around 14 months. This is because participants joined at different times. The trial started in March 2024 when the first informed consent was given and ended in June 2025.

What were the results?

The main goal of the trial was to evaluate the safety of TV-44749 when given to Chinese participants with schizophrenia.

Researchers looked at how many participants had adverse events following administration of TV-44749 (treatment emergent):

TV-44749 Treatment Period and Follow-up:	Cohort 1 (318mg) out of 11 participants	Cohort 2 (425mg) out of 4 participants	Cohort 3 (531mg) out of 6 participants	Total out of 21 participants
Number of participants with at least 1 treatment emergent adverse event(s)	10 (91%)	3 (75%)	6 (100%)	19 (90%)
Number of participants with at least 1 treatment emergent serious adverse event(s)	0	0	1 (17%)	1 (5%)
Number of participants with at least 1 injection site adverse event(s)	3 (27%)	0	4 (67%)	7(33%)

Did the participants have medical problems during the trial? If so, what were they?

This summary describes medical problems that the participants had during the trial that the doctors thought might be related to the trial treatment. These medical problems are called adverse reactions. These adverse reactions may or may not have been caused by the trial

treatment. A lot of research is needed to know whether a treatment causes a medical problem.

The adverse reactions reported in this summary reflect only the trial doctor's initial opinion about which individual events had a reasonable possibility of being related to the trial treatment. The trial doctor looked at each individual event without seeing all of the trial data and made a judgment about whether there was a reasonable possibility the event was related to the trial treatment in real time during this trial.

Events from other participants or other trials may not match these judgments. The trial sponsor has access to other participants' data and may or may not agree with the trial doctor's initial judgment about whether there was a reasonable possibility the event was related to the trial treatment.

Did the participants have any serious adverse reactions?

Some adverse reactions are considered "serious". Examples of serious adverse reactions are those that are life threatening, cause long-term problems, or need hospital care for treatment.

In the TV-44749 Treatment Period and Follow-up, there was 1 participant out of 21 (5%) with a serious adverse reaction of slow heart rate (sinus bradycardia).

There were no serious adverse reactions reported in the Oral Olanzapine Treatment Period and Washout.

In the Oral Olanzapine Treatment Period and Washout, there was 1 participant out of 24 (4%) who discontinued the trial due to an adverse reaction of slow heart rate (sinus bradycardia).

No participants discontinued the trial due to adverse reactions in the TV-44749 Treatment Period and Follow-up.

How many participants had non-serious adverse reactions? What were they?

In the Oral Olanzapine and Washout period, 6 participants out of 24 (25%) reported non-serious adverse reactions.

In the TV-44749 Treatment Period and Follow-up, 14 participants out of 21 (67%) reported non-serious adverse reactions.

The tables below show the adverse reactions that happened to more than one participant within a cohort.

These were the most common adverse reactions during the Oral Olanzapine Treatment Period and Washout:

Adverse Reaction	Cohort 1 (10mg/day) (out of 12 participants)
Trouble sleeping (insomnia)	2 (17%)

These were the most common adverse reactions during the trial in the TV-44749 Treatment Period and Follow-up:

Adverse Reaction	Cohort 1 (318mg) (out of 11 participants)
High level of triglycerides (a type of fat) in the blood (hypertriglyceridaemia)	4 (36%)
Itchiness at the injection site (injection site pruritus)	2 (18%)
Tiredness (fatigue)	2 (18%)
Raised liver enzyme level (alanine aminotransferase increased)	2 (18%)
High blood sugar levels (hyperglycaemia)	2 (18%)

Adverse Reaction	Cohort 3 (531mg) (out of 6 participants)
Itchiness at the injection site (injection site pruritus)	2 (33%)
Hardening at the injection site (injection site induration)	2 (33%)

There were other adverse reactions during the trial, but none of these happened to more than one participant within a cohort.

How has this trial helped?

The results of this trial helped researchers learn more about the safety of TV-44749 in Chinese adults with schizophrenia.

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 treatment works. This summary only shows the results from this trial. Other trials might have different results.

Where can I learn more about this trial?

You can find more information about this trial on the websites below.

ClinicalTrials.gov → NCT06253546

Sponsor: **Teva Branded Pharmaceutical Products R&D LLC**
145 Brandywine Parkway
West Chester, Pennsylvania 19380 USA
1-888-483-8279
USMedInfo@tevapharm.com