Clinical Study Results

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Study Sponsor: UCB Biopharma SRL

Treatment Studied: Rotigotine

Protocol Number: SP1037

Short Study Title: A study to learn if rotigotine reduced symptoms in Chinese participants with advanced-stage Parkinson's disease

Thank you!

UCB thanks all the participants of this study. All the participants helped the researchers learn more about using rotigotine in people with advanced-stage Parkinson's disease.

This is a summary of the main results of this study. An independent, non-profit organization called CISCRP helped prepare this summary of the study results.

We think it is important to share the results with the participants and the public. We hope this summary helps the participants understand and feel proud of their important role in medical research.

The purpose of this summary is only to share information. If you need medical advice, please contact your doctor. If you participated in this study and have questions about the results, please speak with a study doctor or study staff.

Why was the research needed?

Before a treatment is available to all patients, researchers do clinical studies to get information about how well the treatment works and about how safe it is.

The researchers in this study wanted to learn if rotigotine worked in a large number of Chinese participants with advanced-stage Parkinson's disease. They also wanted to learn if the participants had any medical problems during the study.

In people with Parkinson's disease, symptoms appear over time and slowly get worse. The most common symptoms are slowness of movement, uncontrollable shaking, and stiffness of muscles. Advanced-stage Parkinson's disease means that symptoms have gotten worse over time, and that patients are in need of treatment with a specific drug called levodopa. Levodopa is also called L-dopa.

Doctors believe that the symptoms of Parkinson's disease are due to low levels of a molecule called dopamine in the brain. Treatments for Parkinson's disease work by increasing the levels or activity of dopamine in the brain. Over time, the effects of some treatments for Parkinson's disease can wear off. When this happens, people have time during the day when their Parkinson's symptoms get worse. This is known as "off" time.

Rotigotine works by increasing dopamine activity in the brain. In this study, the researchers wanted to learn if rotigotine helped reduce the amount of "off" time in participants already getting treatment with L-dopa.

What were the main questions studied?

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

- Did the participants' "off" time change after getting rotigotine?
- What medical problems did the participants have during the study?

Who participated in the study?

There were 346 men and women in China with advanced-stage Parkinson's disease who participated in this study and took treatment in the study. The participants were 36 to 85 years old.

In this study, the researchers planned to include participants with advanced-stage Parkinson's disease who:

- Had Parkinson's disease for more than 3 years
- Were over 30 years old
- Were getting steady treatment for Parkinson's with L-dopa but were having "off" time every day
- Did not have other serious conditions

Each participant was in the study for just over 6 months, but the whole study lasted for 26 months. The study started in July 2012 and ended in October 2014.

What treatments did the participants take?

The participants in this study got rotigotine or a placebo through a skin patch worn for 1 day at a time, every day.

The placebo patches looked like rotigotine patches but did not have any rotigotine in them. The researchers used the placebo to help make sure the effects of rotigotine they found in the study were actually caused by it. The participants stayed on a steady dose of their usual L-dopa treatment during the study.

The doses of rotigotine were measured in milligrams per 24 hours, also called mg/24 h. The patches were different sizes depending on the dose of rotigotine. The participants got increasing doses during the study. The participants got each dose of the patch for 1 week before getting the next dose.

None of the participants, study doctors, or study staff knew which treatment each participant was getting. UCB staff also did not know. Many studies are done this way because knowing what treatment the participants are getting can affect the results of the study. After the study was completed, UCB learned what treatment each participant got so they could create a report of the results.

The researchers used a computer program to randomly choose if the participants got rotigotine or the placebo. This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

There were 174 participants who got rotigotine and 172 participants who got the placebo during this study.

The chart below shows the treatments the researchers planned to study.

174 participants got rotigotine.

172 participants got the placebo.

The participants got rotigotine or the placebo through a skin patch worn for 1 day at a time.

The participants wore a new skin patch every day.

The participants got increasing doses every week for the first 7 weeks.

The doses were increased from 4 mg/24 h to a maximum of 16 mg/24 h.

What happened during the study?

This section shows how the study was planned to be done.

Before joining the study, the participants visited their clinic 1 time. All the participants first learned about the study and then decided to join. This is called “informed consent.” Then, the study doctors and study staff asked the participants about their medical history and checked their health to make sure they could join the study. This part lasted up to 4 weeks.

There were 3 parts of this study:

Part 1 lasted for up to 7 weeks. The participants visited their clinic 7 times. During this part, the participants had their dose increased by 2 mg/24 h every week until the optimal dose for the participant was reached. The optimal dose was the dose at which the participant had the most benefits with the least medical problems. This was different for each participant.

Part 2 lasted for 12 weeks. The participants visited their clinic 5 times. During this part, the participants stayed on their optimal dose from Part 1.

Part 3 lasted up to 12 days. The participants did not visit their clinic. During this part, the participants had their dose slowly decreased by 2 mg/24 h every 2 days until they stopped taking it.

During the study:

The participants wore the rotigotine skin patch or the placebo skin patch for 1 day at a time, every day.

The study doctors kept track of any medical problems reported by the participants or observed by the study doctors or study staff.

The participants gave blood and urine samples at some clinic visits.

The participants kept track of their “off” time in a diary and answered questionnaires about their overall health and their symptoms.

The study doctors checked the participants’ heart health using an electrocardiogram, also called an ECG at some clinic visits.

After getting the last treatment, the participants visited their clinic 1 time. The study doctors asked about their health and any medical problems they were having. This part lasted up to 4 weeks.

What were the results of the study?

This is a summary of the main results from this study. These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.

Deciding which treatments work best usually takes results from several studies. Other studies may provide new information or different results. Always talk to a doctor before making any treatment decisions.

The results below include 338 out of 346 participants. This is because some participants left the study before getting at least 1 “off” time measurement after starting treatment.

Did the participants' "off" time change after getting rotigotine?

Yes. In this study, the participants who got rotigotine had less "off" time compared with the participants who got the placebo.

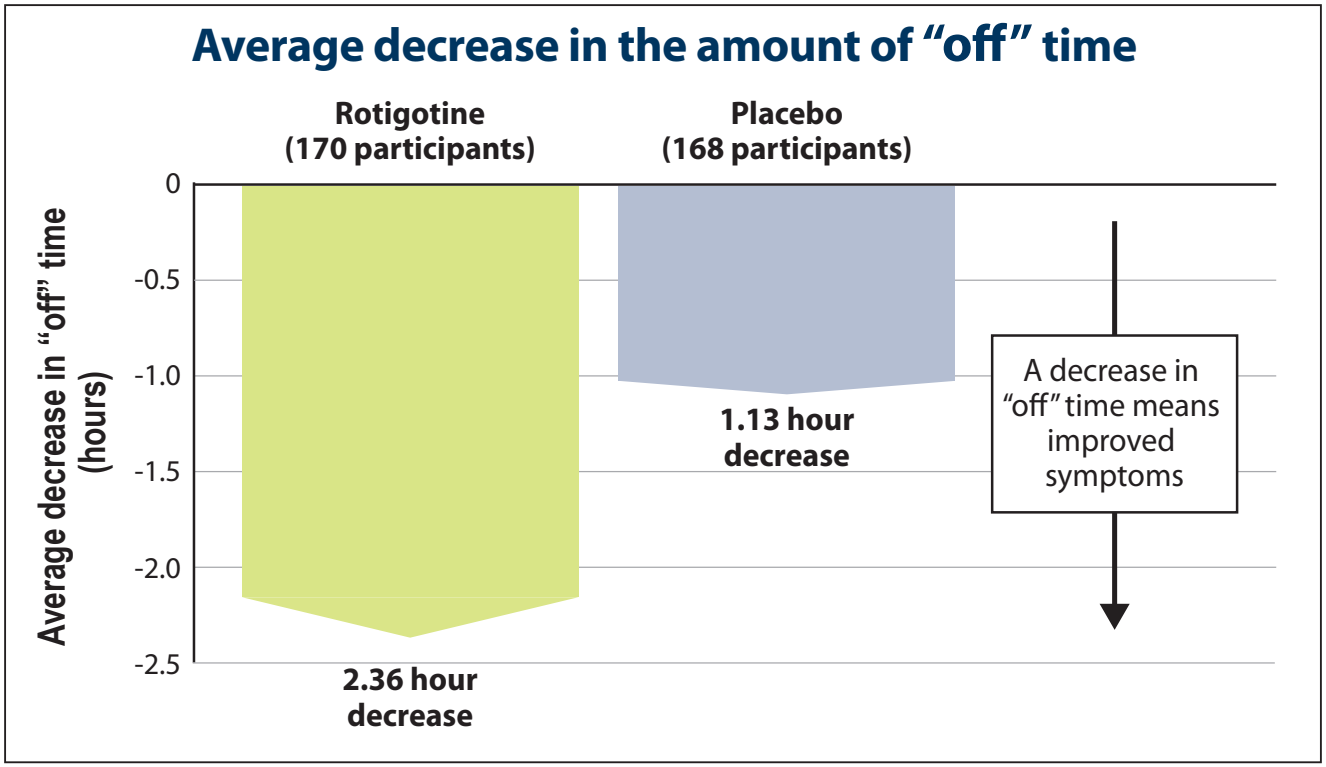
To answer this question, the researchers looked at the participants' diary entries about their Parkinson's symptoms. These entries included the amount of time each day that the participants' Parkinson's symptoms got worse. This was called "off" time. The participants kept track of their "off" time before and after they got treatment in the study. The researchers calculated the average amount of "off" time. They compared the average amount of "off" time before the participants got study treatment and at the end of Part 2.

The researchers found that at the end of Part 2, the average amount of "off" time decreased in the participants who got rotigotine and those who got the placebo. They found that the average decrease was bigger in the participants who got rotigotine.

At the end of Part 2 of the study, the average amount of "off" time had:

- decreased by an average of 2.36 hours in the participants who got rotigotine
- decreased by an average of 1.13 hours in the participants who got the placebo

The graph below shows these results.



What medical problems did the participants have?

This section is a summary of the medical problems the participants had during the study that the study doctors thought might be related to the treatments. These medical problems are called “adverse reactions”. Some participants may have had more than 1 adverse reaction.

An adverse reaction is considered “serious” when it puts the participant’s life at risk, requires hospitalization, causes disability, causes a baby being born with medical problems, or may have turned into 1 of these problems if not treated.

These adverse reactions may or may not be caused by the treatments in the study. The results from several studies are needed to decide if a treatment causes an adverse reaction.

How many participants had serious adverse reactions?

There were 0.6% of participants who got rotigotine and had a serious adverse reaction during the study. This was 1 out of 174 participants getting rotigotine. This participant had heavy bleeding in the gastrointestinal tract.

None of the participants who got the placebo had a serious adverse reaction.

None of the participants died due to serious adverse reactions.

How many participants had any adverse reactions?

In this study, adverse reactions happened in:

- 44.8% of participants who got rotigotine during the study. This was 78 out of 174 participants.
- 32.6% of participants who got the placebo during the study. This was 56 out of 172 participants.

What adverse reactions did the participants have?

The table below shows the adverse reactions that happened in 5% or more participants in either treatment group. This means they happened in at least 1 out of every 20 participants in either of the treatment groups. There were other adverse reactions, but these happened in fewer participants.

The most common adverse reaction overall was itchiness.

Adverse reactions in 5% or more of participants in either treatment group

Adverse reaction	Rotigotine (out of 174 participants)	Placebo (out of 172 participants)
Itchiness	6.9% (12)	5.2% (9)
Dizziness	8.0% (14)	2.9% (5)
Nausea	8.0% (14)	1.2% (2)
Uncontrolled movement	6.3% (11)	3.5% (6)

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using rotigotine in Chinese people with advanced-stage Parkinson's disease.

Deciding which treatments work best for patients almost always takes results from several studies. This summary shows only the main results from this one study. Other studies may provide new information or different results.

The purpose of this summary is only to share information. If you need medical advice about your own health or situation, please contact your doctor.

The results of this study may be used in other studies to compare rotigotine with other treatments for people who have advanced-stage Parkinson's disease.

At the time this study ended, further clinical studies in Parkinson's disease with rotigotine were planned.

Where can I learn more about this study?

You can find more information about this study at the website listed below:

- www.clinicaltrials.gov/ct2/show/study/NCT01646255

If you have questions about this study, UCB contact information is available at: www.ucb.com/UCBCares

Study Information

Protocol Number: SP1037

Study Sponsor: UCB Trading (Shanghai) Co, Ltd, sponsored this study. It is referred to as UCB in this summary

Full Study Title: A Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled Study of the Efficacy and Safety of Rotigotine Transdermal Patch in Chinese Subjects with Advanced-stage, Idiopathic Parkinson's Disease Who Are Not Well Controlled on Levodopa

National Clinical Study Number: NCT01646255

Thank you!

Participants in clinical studies belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

Glossary

Description	Also called
Heavy bleeding in the gastrointestinal tract	The gastrointestinal tract is the tube that carries food from the mouth to out of the body. Heavy bleeding anywhere along the tube is called "gastrointestinal haemorrhage."
Itchiness	Also called "pruritus"
Uncontrolled movement	Also called "dyskinesia"

This summary was last updated on 11 September 2020.
The final clinical study report is dated 3 March 2015.