

Clinical Study Results



Study Sponsor: UCB Biopharma SRL

Treatment Studied: Rotigotine

Protocol Number: SP0914

Short Study Title: A study to learn if rotigotine reduced symptoms in Chinese participants with early-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 early-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 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 participants with early-stage Parkinson's disease. They also wanted to learn if the participants had any medical problems during the study.

In people with early-stage 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. These types of symptoms related to movement are called motor symptoms.

Doctors believe that these motor symptoms are due to low levels of a molecule called dopamine in the brain. Rotigotine works by increasing the levels or activity of dopamine in the brain. In this study, the researchers wanted to find out if the participants had fewer motor symptoms after getting rotigotine through a skin patch.

What were the main questions studied?

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

- Did rotigotine reduce the participants' motor symptoms and help with their ability to do daily activities?
- What medical problems did the participants have during the study?

Who participated in the study?

There were 247 men and women in China with early-stage Parkinson's disease who participated and took treatment in this study. The participants were 31 to 81 years old.

To make sure the participants could join the study, the researchers used a common questionnaire about Parkinson's disease. This is called the Unified Parkinson's Disease Rating Scale, also called the UPDRS. The researchers looked at Part 3 of the UPDRS, which asks about motor symptoms. The participants received "scores" based on their answers. Part 3 is scored out of 56 points. A higher score means more severe symptoms.

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

- Had Parkinson's disease for 5 years or less
- Were over 30 years old
- Had a UPDRS Part 3 score of at least 10
- Did not have other serious conditions
- Were not already getting certain other drugs for Parkinson's disease

Each participant was in the study for about 9 months, but the whole study lasted for nearly 2 years. The study started in June 2012 and ended in May 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 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. This was done until the participants' Parkinson's symptoms were gone or greatly reduced, without too many medical problems. The participants got each dose of rotigotine 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 124 participants who got rotigotine and 123 participants who got the placebo during this study.

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



124 participants got rotigotine.



123 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 of rotigotine every week for the first 4 weeks.



The doses of rotigotine increased from 2 mg/24 h to a maximum of 8 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 4 weeks. The participants visited their clinic 4 times. During this part, the participants had their dose increased 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 24 weeks. The participants visited their clinic 6 times. During this part, the participants stayed on their optimal dose from Part 1.

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Part 3 lasted for 1 week. The participants visited their clinic 1 time. During this part, the participants had their dose slowly decreased 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 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 visits.

After the study, the participants visited their clinic 1 time. The study doctors asked about their health and any medical problems they were having. This part lasted 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 244 out of 247 participants. This is because some participants left the study before getting at least 1 measurement.

Did rotigotine reduce the participants' motor symptoms and help with their ability to do daily activities?

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Yes. In this study, the participants who got rotigotine had a bigger reduction in motor symptoms than those who got the placebo. They were also more able to do daily activities than the participants who got the placebo.

To answer this question, the researchers used Parts 2 and 3 of the Unified Parkinson's Disease Rating Scale, also called the UPDRS. Part 2 asked about the participants' ability to do daily activities and is scored out of 52 points. Part 3 asked about the participants' motor ability. The participants answered the questionnaire before and after getting treatment. They received "scores" based on their answers to the UPDRS. A higher score meant more severe symptoms.

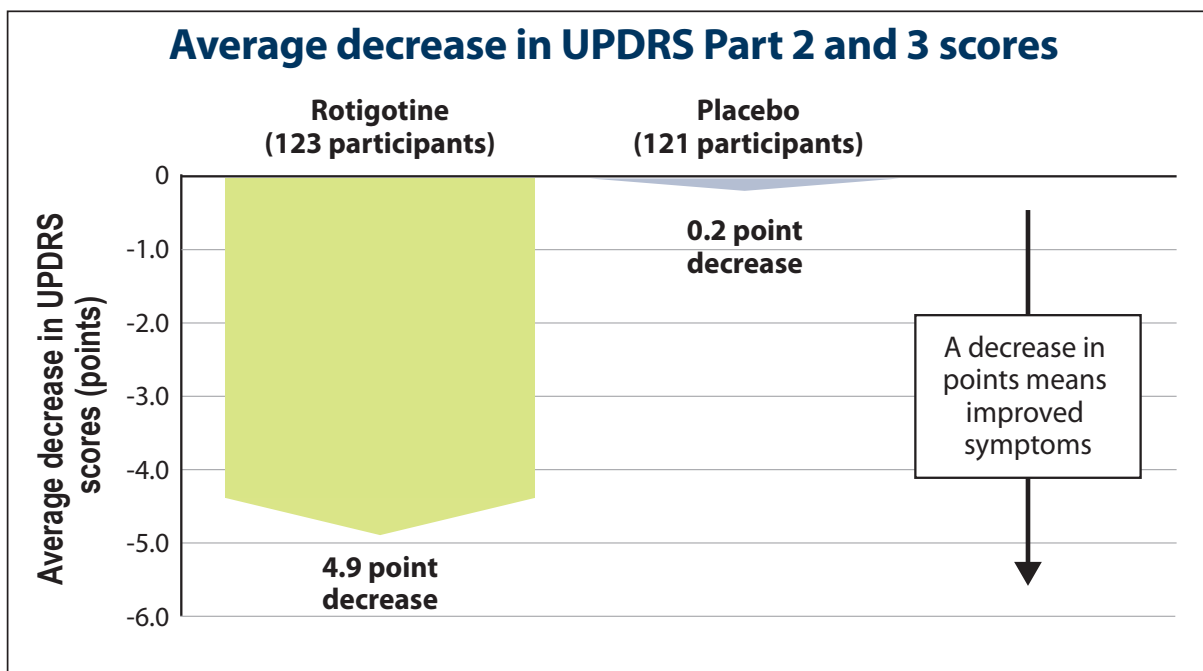
The researchers added together the scores from Part 2 and Part 3. They compared the participants' scores before and after getting study treatment at the end of Part 2 of the study.

The researchers found that, at the end of Part 2 of the study, the average scores decreased in the participants who got rotigotine and in 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 decrease in the UPDRS Part 2 and Part 3 total scores was:

- 4.9 points in the participants who got rotigotine
- 0.2 points 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?

None of the participants had serious adverse reactions in this study.

How many participants had any adverse reactions?

In this study, adverse reactions happened in:

- 36.3% of participants who got rotigotine during the study. This was 45 out of 124 participants.
- 27.6% of participants who got the placebo during the study. This was 34 out of 123 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.

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The most common adverse reaction was itchiness.

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

Adverse reaction	Rotigotine (out of 124 participants)	Placebo (out of 123 participants)
<u>Itchiness</u>	7.3% (9)	3.3% (4)
Nausea	7.3% (9)	2.4% (3)
<u>Sleepiness</u>	6.5% (8)	2.4% (3)
Dizziness	5.6% (7)	3.3% (4)
<u>Skin redness</u>	5.6% (7)	1.6% (2)

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 early-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 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/NCT01646268

If you have questions about this study, UCB contact information is available at:

www.ucb.com/UCBCares

Study Information

Protocol Number: SP0914

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 the Rotigotine Transdermal Patch in Chinese Subjects with Early-Stage Idiopathic Parkinson's Disease

National Clinical Study Number: NCT01646268

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
Itchiness	Also called "pruritis"
Skin redness	Also called "erythema"
Sleepiness	Also called "somnolence"



This summary was last updated on 11 September 2020.
The final clinical study report is dated 21 November 2014.