20200207
#27934648.0

IRB Approved at the
Protocol Level
Jun 30, 2020

Feel Something?
Do Something.

If you suffer from
painful diabetic peripheral neuropathy,
you may benefit from this clinical study.

Welcome to the overview of the RELIEF DPN-1 clinical trial

RELIEF **DPN-1**

Welcome and thank you for taking time with your doctor to learn about the RELIEF DPN-1 Study

You are being asked to participate because you have DPN and have symptoms that may qualify you for this important research study.

We are testing a study drug to learn more about its safety and effectiveness.

The RELIEF DPN-1 Clinical Trial will study LX9211, a new potential drug for the treatment of DPNP.

- The manufacturer is seeking volunteers to investigate the drug's safety and effectiveness.

Voluntary Participation

- Your participation in the RELIEF DPN-1 clinical trial is voluntary.
- You are free to say yes or no.
- If you are considering participating, please discuss this clinical trial with your family and personal physician.

Introduction

You are being asked to participate because you have DPN and have symptoms that may qualify you for this important research study.

We are testing a study drug to learn more about its safety and effectiveness.

The study uses a placebo, which looks like the drug, but contains no medicine. You will be randomly assigned 1 of the 2 dosages of the study drug or placebo over a 11-week period. More on this later...

Who will participate in the study?

Who will participate in the study?

- Participants will include men and women of non-childbearing potential between 18 and 75 years of age.
- The study will take place at 30 sites across the United States.
- Approximately 300 patients are expected to enroll in this study. Up to 90 of those may be recruited for special sub-studies.

The Study Drug

LX9211 is a tablet taken by mouth once daily in the morning

You will be randomly assigned 1 of the 2 dosages or placebo.

The Study Drug

The study drug, LX9211, is a tablet taken by mouth. During the trial you may be given 1 of 2 different dosages or a placebo (a pill that looks like the study drug, but that does not contain any active ingredients from the drug.)

Participants will be randomly and evenly assigned to 1 of 3 treatment groups:

- **Group 1:** LX9211 100 mg* / 10 mg**, once daily
- **Group 2:** LX9211 200 mg* / 20 mg**, once daily
- **Group 3:** Placebo, once daily

* Loading dose (Day 1)

** Maintenance dose (Day 2 - Week 11 Visit)

Implementation of the treatment randomization schedule will be centralized.

If you participate, you will visit the study center 7 times within 15 weeks. The clinical study will consist of 4 phases:

What will happen during the study If you decide to take part in this research study, you will be required to visit the study center 7 times within 15 weeks.

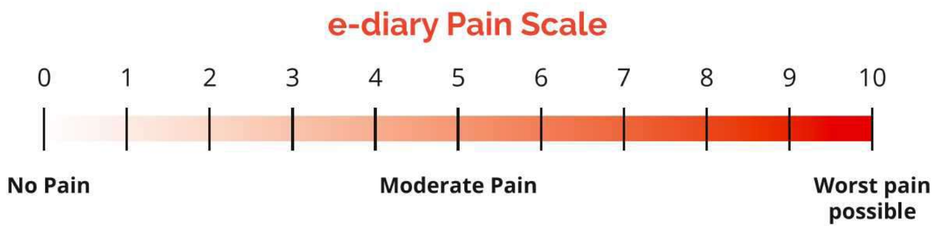
It is important that you come to all study visits at the scheduled time. If you cannot attend at the scheduled time, please set up a new time as soon as possible.

The clinical study will consist of 4 phases:

- Screening
- Run-In
- An 11 week assesment period.
- A Final Safety Follow-up

Screening Period

You will have a screening visit to check if you are eligible for the study based on a list of inclusion and exclusion eligibility criteria. This period can last up to 2 weeks.



Run-in Period

- You will start taking study drug.
- On Day 1, while you are at the study center, you will take 4 tablets, a “loading dose”.
- For the remaining days of this phase you will then take 1 tablet each morning.
- Each evening you will complete your e-diary and rate their DPN pain on an 11-point scale where zero = no pain and eleven = the worst possible pain.
- You are not allowed to take any pain medication (pain killers) during this phase.

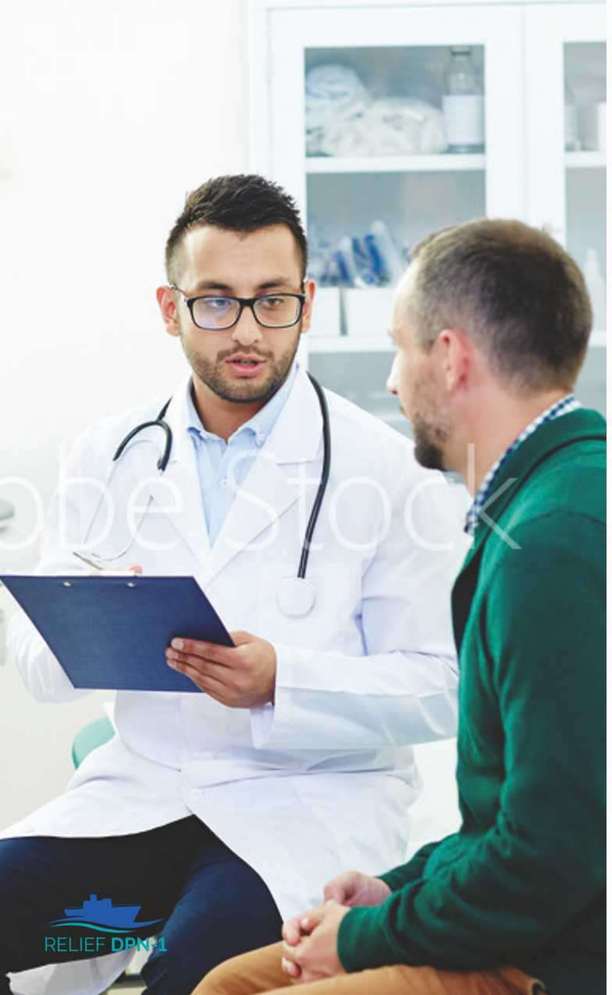
11 Week Assessment Period

- For 11 weeks, we will track the effect that the study drug has on you.
- On Day 1 of this period, you will be given another loading dose at the study center and you will be observed for 2 hours following this dose.
- After this, you will take a daily tablet, as you did in the Run-in Period.
- On days where you visit the study center you will not take your tablet until after the visit. You will also complete your e-diary every evening.
- On Day 1 you will also be given a bottle of acetaminophen, which you can use if you need it (up to 3 grams per day).
- At the end of the study, you will come to the study center for a final visit.

During the screening visit, patients may choose to participate in one or both of the 2 optional sub-studies.

The first optional sub-study which will include up to 30 patients confined to a clinical research unit for 3 (over- night stays) for intensive blood sampling.

The second optional sub-study will be a telephone interview to gain insight into the patient’s experiences with symptoms of DPN pain.



What will I be expected to do while in the study?

Taking part in a research study can be an inconvenience to your daily life and your family. Please consider the time commitments and responsibilities.

Withdrawal

Unable to tolerate your DPN pain during the study? It is preferred that you not take any additional pain medications throughout the study. However there are exceptions.

What will I be expected to do while in the study?

Taking part in a research study can be an inconvenience to your daily life. Please consider the time commitments and responsibilities as a research patient when you are deciding to take part.

Your responsibilities as a study patient may include the following:

- Telling the truth about your medical history and current conditions.
- Agreeing to be contacted by the study team if necessary.
- Coming to all study visits.
- Telling the study doctor about any problems you have during the study.
- Taking the study drug as directed by the study doctor and study staff.
- Accurately filling out your e-diary and returning it.

Withdrawal

- Unable to tolerate your DPN pain during the study?
- It is preferred that you not take any additional pain medications throughout the study.
- If you experience unacceptable pain, there are exceptions.
- Please speak with your study doctor about rescue medications if needed.

Risks and discomforts of the study

You may experience side effects that are not yet known and cannot be foreseen.

Pregnancy risks - Female participants

You must not be pregnant or breast feeding during the course of the study. The effects of the drug may harm an uborn child.

Pregnancy risks - Male participants

The effects of the drug may harm an uborn child. You will be expected to use acceptable methods of contraception.

Risks and discomforts of the study

It is important to be aware that there may be side effects that are not yet known and cannot be foreseen.

Pregnancy risks - Female participants

- The study drug may harm an unborn child.
- Effects of breast feeding baby are not known.
- You must not be pregnant or breast-feeding during the course of the study.
- You must not become pregnant during the course of the study.
- You will not be eligible to participate in the study if you are able to become pregnant, trying to become pregnant, or breast-feeding.

Pregnancy risks - Male participants

- The study drug may harm an unborn child.
- You must inform your female partner of your participation in this study.
- You must both agree to use a highly effective method of contraception such as IUDs, condoms, female condoms, birth control pills, tubal ligation, or vasectomy.

Frequently Asked Questions

- Are there benefits?
- Will it cost me anything and will I be payed?
- What if I am injured?
- Will my health information be confidential?
- What if new information becomes available?
- Premature end of the study or treatment?
- Who can I contact for more information?

Are there any benefits to being in the study?

- You may or may not receive any benefit from being in the study.
- It is possible that you may get better, stay the same, or get worse.
- If you take part in this study, other people with DPN pain may be helped by the research.

Will it cost me anything and will I be paid to be in the study?

- The study drug and all tests and procedures required are provided at no cost to you.

What if I am injured during the study? Am I insured?

During the Clinical trial the sponsor has insurance in accordance with the federal government in case you are injured .

The Sponsor will pay necessary medical expenses for any injury you suffer that is a direct result of taking part in the study; where the injury is a result of taking the investigational drug being tested or any test or procedure you received as part of the clinical trial protocol.

No compensation is paid for:

- Pain and suffering.
- Health damage or worsening of existing diseases if these would also occur or persist if you would not participate in this trial.
- Health damages which are caused when the patient acts contrary to the advice of study personnel.
- We also wish to point out that you're not insured in route to and from the study site.

Will my protected health information be kept private?

Your identity and your medical information will be kept confidential.

The sponsor and those working for the sponsor may use the health data sent to them:

- to investigate whether the study drug works and is safe;
- to compare the study drug to other drugs;
- for other activities (such as development and regulatory) related to the study drug.

You may withdraw your consent at any time. If you withdraw consent for study participation, your consent to data or sample processing already collected may still be used, however, no new information or samples will be collected, and you may also request that no new analyses be performed after withdrawal.

Your full identity will not appear on any of the study documents or samples or scans collected and retained by the sponsor for their analyses. Only a unique patient number for the study will link the data or samples to you. These data may contain your gender and race, as well as any medical and scientific data required by the study.

What if new information becomes available?

- During the study, new information about risks and benefits of the study drug or DPNP may be known.
- Your study doctor will discuss with you any new information that may affect your eligibility or willingness to continue to participate in the study.
- In all cases, your study doctor will offer medical care to suit your needs and/or medical condition.

Premature end of the study or study treatment

This study or the study treatment may be stopped without your permission for a variety of reasons by the study doctor and/or the sponsor:

- The drug has been shown as ineffective.
- The drug has been shown to work and there is no need for further investigation.
- Decisions made in the commercial interests of the sponsor.
- Decisions made by regulatory authorities.
- Participation in the study is not beneficial to you.
- You experience unacceptable side effects.
- Your failure to keep appointments or take medications, as directed.
- You need to receive other treatments for your medical condition.

Who can i contact for more information?

Please contact the study staff if you have any questions about:

- study
- procedures
- risks and benefits
- alternative courses of treatment
- or in cases of emergency

The names and telephone numbers of the study staff to contact will be provided to you.