Pharmaceutical companies use research studies like this one to learn more about investigational drugs before they are made available to the public as approved treatments. The results of this study will provide information about the effectiveness of the investigational drug being evaluated. By taking part in this study, you will be making an important contribution to Cerebral X-Linked Adrenoleukodystrophy (cALD) treatment research.

To learn more about this study, please contact:
Jordan Goodman, Study Coordinator
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443-923-2769
Who is eligible to participate in this study?

Your doctor will let you know whether you are eligible to take part in the study. The following are just some of the criteria that your doctor will assess:

- **18 years old and aged ≥18 years.**
- **≥0.5 Loes score ≥0.5 and ≤12.**
- **Have a genetic confirmation of X-ALD.**
- **Have a normal adrenal function.**
- **Not have a major functional disability excepting “wheelchair bound” or “total incontinence” and not have major cognitive impairment.**
- **Have a progressive CALD, defined as Gd+ brain lesions.**

All study-related visits, tests, and study medicine will be provided without costs to you. In addition, assistance to travel to the study clinic will be provided, and you will be reimbursed for the expenses related to the study travel.

What will happen during this study?

If your doctor considers that you meet all the study's eligibility criteria, he will schedule a first study visit, named Screening Visit, and he will hand you over an informed consent form with further information about this study that you will have to sign in case you agree to take part in the study and then, he will assess and test you and determine if you could be enrolled in this study or not.

This study has 2 parts: a double-blind period and an open-label extension.

In the double-blind period of this study, the leriglitazone will be compared to a placebo. A placebo is a treatment that looks and tastes exactly like the study medicine but does not contain any active ingredient. The first visit of this part will be the Baseline Visit, where the study doctor re-confirm your eligibility and you will be randomly assigned the study treatment: leriglitazone or placebo.

During this double-blind period, you will have 1 visit each month for 3 months, then 1 every 3 months thereafter. Visits at months 1, 3, 9, and 12 may be conducted either at your home or at your usual healthcare clinic site by phone. At 3, 6, 9, and 12 months you will receive phone calls from your doctor, and the remaining visits will take place at the study clinic. Home visits will be supported by a nurse or study personnel.

Your participation in the double-blind period is expected to last a maximum of 36 months. But, 2 occasions during this period (March 18 and Month 27), independent experts will check the study results to assess if MIN-102 is working. This is called an “interim assessment”. If, at either of these interim assessments, it is determined that leriglitazone is working, the double-blind period will end, the open-label extension will begin, and all subjects will start receiving leriglitazone.

If the results of the interim assessment confirm that leriglitazone is working, you will continue receiving the study treatment (placebo or leriglitazone) until Month 36. After this time, the open-label extension will begin, and you will start receiving leriglitazone.

What are the benefits and risks related to this study?

As with any research study, you may not personally benefit from participation in this study. Results from this study may benefit others in the future. It is also possible that you could experience a side effect while in this study. Before you begin the study, the study staff will discuss with you the risks related to participating in this study.

Because research studies can affect the health and safety of participants, you will be closely monitored during this study. Researchers for this study designed a protocol, which describes all study procedures in complete detail, and they will ensure that the procedures will be followed exactly. An independent review board is also an independent safety monitoring board that monitors the participants' safety throughout the entire study. In this study, the leriglitazone will be compared to a placebo. A placebo is a treatment that looks and tastes exactly like the study medicine but does not contain any active ingredient. The first visit of this part will be the Baseline Visit, where the study doctor re-confirm your eligibility and you will be randomly assigned the study treatment: leriglitazone or placebo.

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