BE PART OF SHAPING THE FUTURE FOR THE TREATMENT OF WILSON DISEASE

THE ALXN1840 WILSON DISEASE COPPER BALANCE STUDY INFORMATION BROCHURE

Learn more about the study and see if being a participant in the study is right for you

ALXN1840 is not approved for the treatment of Wilson disease. The safety and efficacy of ALXN1840 for the treatment of Wilson disease are currently being studied.
WHAT IS THE MEDICINE THAT IS BEING STUDIED?
Alexion is investigating a new medicine for the treatment of Wilson disease.

WHAT IS THE ALXN1840 WILSON DISEASE COPPER BALANCE STUDY ABOUT?
Research studies help to make advances in medical science and help to develop new and improved treatment options, with the aim of testing whether a potential new medicine is tolerable and effective.

Copper is an important nutrient that helps to maintain a healthy body. The body requires only a very small amount of copper, which is taken into the body via food and drink. In patients with Wilson disease, excess copper is not properly removed from the body via urine and feces, leading to increased copper levels in organs such as the liver and brain. Copper build-up may cause severe damage, most commonly in the liver and brain, when left untreated.

In the ALXN1840 Wilson disease copper balance study, the aim is to find out whether ALXN1840 is able to help restore copper balance by promoting the removal of more copper from the body than what is taken in through food and drink, creating what is known as a negative copper balance.

WHAT IS INVOLVED FOR PARTICIPANTS IN THE STUDY?
Taking part in the study is voluntary and you may leave the study at any time if you change your mind.

You would take part in the study for approximately 6 weeks, and would need to become an inpatient at the study research facility on two occasions for 17 days each. These inpatient periods are scheduled to appropriately monitor food intake and to collect urine, stool, and blood samples. You would also have the option to remain at the facility for the duration of the study, for a total of approximately 48 days.

During these periods at the research facility, meals would be provided, which would allow for the amount of copper you take into the body to be controlled and measured. Urine and stool samples would be collected, and blood samples would be taken on several occasions.

From day 1 to day 28 of the study, you would receive 15 mg of ALXN1840 per day. Based on the findings from the sample collections from this period, you may then be given an increased dose of 30 mg per day from day 29 to day 39.

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WHO IS ALLOWED TO TAKE PART IN THE STUDY?

If you have a confirmed diagnosis of Wilson disease, then participation in the study could be right for you. You may be able to take part in the study if you:

- Are male or female and at least 18 years of age
- Are able to stay at the research facility for 17 days on two separate occasions, or throughout the duration of the study for a total of approximately 48 days
- Are not pregnant or planning to become pregnant, and not breastfeeding
- Are willing to tolerate and complete every meal of a controlled diet during inpatient periods, and maintain a low-copper diet as an outpatient
- Are willing to comply with the collection of urine, stool, and blood samples over the duration of the study

To be certain that any effects that are observed in the study can be attributed to ALXN1840, other medications that you may be taking for Wilson disease would be stopped. If you are currently taking another medication for Wilson disease, you would work with your doctor to safely stop this medication approximately 4 days before the start of the study. For patients taking zinc treatment, you would work with your doctor to safely stop this medication 30 days before the start of the study. If you require treatment for any other conditions, you should tell the study doctor during the screening evaluation before the start of the study. The study doctor would then advise you if these medications, vitamins, or supplements can be taken during the study.

During the time spent at home as an outpatient, you would be required to maintain a low-copper diet. You would be provided with more information about what a low-copper diet should include if you choose to participate in the study.
WHY SHOULD I PARTICIPATE IN THE STUDY?

There are many reasons why people choose to participate in clinical studies. Taking part in the study is an opportunity to contribute to moving science forward and shaping the future of treatment for Wilson disease. You will not receive health benefits from the study. You may learn about your general health or discover an unknown medical condition. The study may help doctors learn about ALXN1840, which will help others.

You would be closely monitored and cared for by dedicated healthcare professionals during the study. As with all medications, there is the potential for participants to experience side effects. There may be risks that we cannot predict. However, medical professionals will be routinely monitoring health and safety throughout the duration of the study.

HOW CAN I GET MORE INFORMATION ABOUT THE STUDY?

If you would like to learn more about the ALXN1840 Wilson disease copper balance study, please contact:

Email: WilsonStudyInfo@celerion.com

Tel: 886-445-7033

Visit: https://clinicaltrials.gov/ct2/show/NCT04573309

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