What to Expect

Participation in the FALCON study is divided into 3 parts:

- **Screening and baseline:** 8-12 weeks
- **Treatment:** 48 weeks
- **Safety follow-up:** 5 weeks

During the treatment period, participants will be randomly assigned (like picking straws) to receive either the study medicine (KL1333) or placebo (no active medication). The study medicine (or placebo) is given twice daily in tablet form.

Neither the participants nor the study team will know who is receiving the study medicine or placebo. Participants will not be able to change which treatment they are assigned.

For every five people who take part, three will receive KL1333 and two will receive placebo.

A safety follow-up visit will occur 5 weeks after the last dose of the study medicine (or placebo).

The total study duration will be approximately 61 to 65 weeks.

FALCON

For more information on the FALCON study and to see if you qualify, please contact us:

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KL1333 2020-104A_Recruitment Brochure_v2.0_UK English_06May2022_
English (US)_19JUL2022

Introducing the **FALCON** study

A research study of a new treatment for primary mitochondrial disease

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About the FALCON Study

The FALCON study is investigating whether the study medicine, KL1333, is effective in improving fatigue levels and ability to carry out day-to-day activities in people who have mitochondrial disease. The study will also help establish the best dose of KL1333 for people to receive.

Who Can Join?

You may be eligible to participate if you:

- Are 18 years or older
- Have a confirmed mitochondrial disease diagnosis due to a known disease-causing gene mutation or deletion in the mitochondrial DNA
- Are experiencing chronic mitochondrial fatigue and myopathy (muscle weakness and/or exercise intolerance)

Other criteria will need to be met to confirm your eligibility for this study.

What Are the Potential Benefits?

If you participate in this study, you will receive:

- The study medicine, KL1333, or a placebo
- Study-related medical assessments throughout the study
- Medical monitoring of your condition
- Reimbursement for travel-related expenses

You may or may not benefit from taking part in this study. However, in the future other people may benefit from this research.

What Are the Potential Risks?

KL1333 has been found to be well tolerated in previous studies. The most common side effects include:

- Abdominal discomfort
- Abdominal distension (bloating)
- Abdominal pain
- Diarrhea
- Nausea

About Clinical Trials

Clinical trials are research studies carefully supervised by doctors and scientists who are looking for better ways to prevent, diagnose, or treat a heath condition. They are required before a new medicine or recommended dosage can be approved and made available to the public.

- Clinical trials follow specific laws to protect the rights, safety, well-being, and confidentiality of study participants
- The results help determine if a product is safe and effective

Participating in a clinical trial is completely voluntary.

Taking part in the FALCON study will provide information about whether or not KL1333 is effective in helping to alleviate symptoms in those who have mitochondrial disease.

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