edelife

A prenatal study for XLHED affected boys

EDELIFE is a clinical study where a potential treatment, ER004, will be given to baby boys affected by XLHED, before they are born in their mother's wombs.

Study participants invited to consider taking part in the EDELIFE are:

- Pregnant women expecting a baby boy, no later than pregnancy week 23, XLHED genetically confirmed
- Male relatives of the pregnant women, XLHED-affected, aged between 6 months and 60 years

Pregnant Woman expecting a baby boy who might be affected by XLHED

Pregnant Woman

V1	V2	V3	V4	V5	V6
Between pregnancy weeks 19 and 24	Week 26	Week 28 to 29	Week 31 to 32	Baby's birth	Month 1

V = Represents a visit

Screening Period: ½ day to 1 day on site

Treatment Period: 2 days (overnight stay) on site for each visit

Follow up Period: ½ day to 1 day on site for each follow-up visit (for both the pregnant woman and the treated child)

Treated child

Follow up Period

V5	V6	V7	V8	V9	V10	V11	V12	V13	V14
Baby's birth	Month 1	Month 3	Month 6	Month 12	Month 18	Year 2	Year 3	Year 4	Year 5

Male relative of the pregnant woman, XLHED-affected

XLHED-affected male relative

V1

Between pregnant woman's Screening vist and her baby being 6-month old

½ day to 1 day on site

What does the Study involve for the Pregnant Woman ?

In total 6 visits to the clinical site in Cardiff, starting from around pregnancy week 19 and until baby is 1-month old.
Need to have a genetic diagnosis of XLHED to take part in the study.
Treatment is given as a course of 3 injections of ER004 into the water around the baby, with approx. 3 weeks between injections.

Treatment visits will be the longest and most demanding

What does the Study involve for the Treated child ?

Once the baby boy is born, 10 visits to the clinical site in Cardiff, including birth, and until he is 5 years old.
Important tests to check on his XLHED symptoms will be conducted each time.

While visits will vary a little, a typical visit is depicted below

What does the Study involve for the male relative ?

Need to collect medical data on untreated male relatives to measure how well ER004 has worked on treated children.
Single visit to the clinical site in Cardiff / No ER004 treatment.
This visit must take place before the treated baby reaches 6 months of age.
Need to have a genetic diagnosis of XLHED to participate in the study, possibility that the study will arrange for one if not available.

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