Trial outline GP and Patient V2.0. dated 15Feb2022 Linked to Protocol version 2.0, dated 28 May 2021

EDELIFE: A PRENATAL STUDY FOR XLHED AFFECTED BOYS

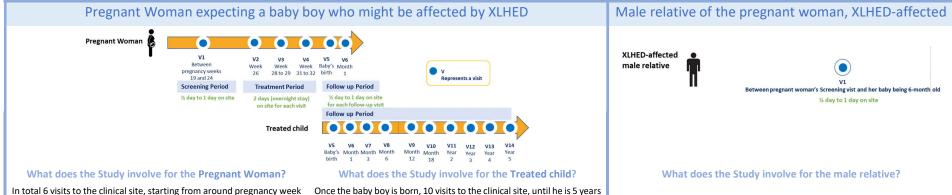
EDELIFE is a clinical study where a potential treatment, ER004, will be given to baby boys affected by X-linked hypohidrotic ectodermal dysplasia (XLHED), by injection into the water surrounding the baby during pregnancy. ER004 is intended to replace a missing protein in XLHED to potentially lead to improved tooth development and sweat gland growth.

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

Pregnant women expecting a baby boy, no later than pregnancy week 23, XLHED confirmed through gene tests

old.

 \checkmark Male relatives of the pregnant women, who carry the same gene variant as her



Once the baby boy is born, 10 visits to the clinical site, until he is 5 years

Important tests to check on his XLHED symptoms will be conducted each time.



Need to have a genetic diagnosis of XLHED to take part in the study.

around the baby, with approx. 3 weeks between injections.

Treatment is given as a course of 3 injections of ER004 into the water

19, including birth, and until baby is 1-month old.

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



Need to collect medical data on untreated male relatives to measure if ER004 has worked on treated children.

Single visit to the clinical site / 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, the study will arrange for one if not available.





You would like to learn more about the study: visit www.clinicaltrials.gov using the identifier NCT04980638 or contact the Study doctor Dr Dorothy Grange grangedk@wustl.edu

