

Phoenix Tissue Repair is looking to recruit more people into its Phase 1/2 clinical trial for PTR-01, a collagen VII replacement therapy for those with Recessive Dystrophic EB (RDEB).

The study is investigating the safety, tolerability, and efficacy of an investigational treatment called PTR-01 (type VII collagen protein). PTR-01 is an investigational product given by intravenous infusion over 1 hour.

This study has been active since early 2019 and has currently enrolled 9 patients.

Patients enrolled in the study are given 3 infusions of PTR-01 (or placebo), followed by 3 doses of placebo (or PTR-01). All subjects will receive both PTR-01 and placebo.

This study involves blood and urine samples and does require skin biopsies. An earlier version of this study required more skin biopsies, but the Sponsor has recently amended the protocol to reduce the number of biopsies. The Sponsor has also allowed for one of the visits to be done remotely.

Study visits occur every 2 weeks and require coming to Stanford. There is a total of 6 infusions. The treatment period is 10 weeks. All travel costs, including accommodations and meals, are covered by the Sponsor. Travel arrangements can also be made for you, so as to alleviate all out-of-pocket expenses.

If you'd like to learn more, please click below:

<https://clinicaltrials.gov/ct2/show/NCT03752905>

In order to be eligible to participate in this study you must:

- Have a diagnosis of RDEB based on genetic analysis
- Be 16 years or older
- Have some but deficient type VII collagen
- Have at least 1 unhealed wound ≥ 20 cm² (about the size of 4 grapes) for at least 6 weeks
- Agree to use contraception if you are of child-bearing potential
- CANNOT have:
 - Known hypersensitivity to any of the inactive ingredients in PTR-01
 - Be pregnant or nursing
 - Have received any investigational product in the past 6 months
 - Anticipate receiving new regimens of antibiotics or other anti-infectives during the trial

If you would like more information or are interested in participating, please visit <https://clinicaltrials.gov/ct2/show/NCT03752905> contact information is listed in the clinical trial posting. Alternatively, you can visit the Sponsor's website at <https://phoenixtissuerepair.com/#patients>