Questions? Call us at (888) 344-8463
foreverlabs.com

STEM CELL CLINICAL TRIAL:

Adipose Derived Mesenchymal Stem Cells for Induction of Remission in Perianal Fistulizing Crohn's Disease

NCT01541579

Sponsor: Tigenix S.A.U.
Collaborator: None

BACKGROUND:

- **Crohn's disease is a chronic inflammatory bowel disease affecting 300 out of every 100,000 people in the USA, Canada, and Europe.**
- **The disease is characterized by transmural inflammation and fistula formation, with perianal fistulas being a common complication.**
- **Perianal fistulas have a severe impact on quality of life and prove to be refractory to conventional treatments.**
- **Very few patients with such a diagnosis obtain long term remission and there is only one approved drug to show efficacy to date.**
- **Adipose stem cells offer a new approach to treat fistulas formed by Crohn's disease due to their ability to elicit an immunomodulatory effect in the presence of inflammatory factors.**

METHOD:

- Adults aged 18 years or older with mildly active Crohn's disease and a history of being refractory to treatment were recruited for the study.
- 212 patients were randomly assigned to either treatment with allogeneic, expanded, adipose derived stem cells (Cx601) or placebo (saline).
- Pelvic MRI scans were performed at screening to guide injections and asses the presence of abscesses. Cx601 cells were previously isolated from the stromal vascular fraction of lipoaspirates. Cells were then expanded under standard growth conditions and cryopreserved.
- Patients in the treated group received an injection of 120 million cells into the adjacent tissue of all fistulas as well as in all internal openings. Patients in the placebo group received identical injections of saline.
- Fistula closures were assessed at 6, 12, 18, and 24 weeks post injection with pelvic MRI scans being performed again at 24 weeks. Severity of disease and quality of life were also measured at baseline and 24 weeks.

RESULTS:

- **The Cx601 cell treated group achieved a higher primary endpoint of combined remission defined as the closure of all treated external openings that were found to be draining at baseline as well as the absence of collections larger than 2 cm in the treated perianal fistula confirmed by MRI versus the placebo.**
- **Reported results of remission were 50% for cell treated compared to 36% for placebo at 24 weeks. In addition, the time to reach remission was shorter for the cell treated group versus placebo with remission occurring in half the time for patients injected with Cx601.**
- **No reports of treatment adverse effects or immune reactions were generated in response to donor specific antibodies with overall safety data indicating that Cx601 was well tolerated.**

CONCLUSION:

- The results of this study propose an encouraging new therapy for patients with Crohn's disease. The use of adipose derived stem cells are well tolerated and minimally invasive with a rapid response being observed versus placebo.
- Future studies should be performed to further test the safety and efficacy of such a therapy.

ASSOCIATED PUBLICATIONS:

- https://clinicaltrials.gov/ct2/bye/rQoPWwoRrXS9-i-wudNgpQDxudhWudNzlXNiZip9Ei7ym67VZR0wSg05SKCVA6h9Ei4L3BUgWwNG0it