

Statistical Analysis Plan (SAP)

Analysis of the Safety and Efficacy of Administering Umbilical Cord Mesenchymal Stem Cell Secretome in Patients With Severe Erectile Dysfunction Non-responsive to Sildenafil

Date : 6 October 2025

1. Outcomes (sign, symptoms and questionnaire result)

One of the study aimed to measure the effect of umbilical cord mesenchymal stem cell secretome administration on outcomes such as pain, hematoma, local bleeding, infection, and changes in IIEF-5, EHS, and morning erections. The Wilcoxon analysis will be used to compare outcomes before and after intervention at various times

2. SPL, FPL and Penis Cicumference

One of the study aimed to measure the effect of umbilical cord mesenchymal stem cell secretome administration on SPL, FPL, and Penis Circumference. The Paired T test wil be used to compare outcomes before and after intervention at various times.

3. PSV and Diameter of cavernosum artery

The study subjects underwent PCDU examination while flaccid to assess both research parameters, namely Peak Systolic Velocity (PSV) and the diameter of the proximal side cavernosum artery lumen before and 1 month after the intracavernosal injection intervention. The difference in PSV of the right and left cavernosum arteries will be analyzed using the Paired T-test.