Title: A RCT Evaluating Efficacy of Type-I Collagen Skin Substitute vs. Human Amnion Membrane in Treatment of Venous Leg Ulcers

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Study Aims

This randomized, controlled clinical trial aimed to compare clinical efficacy, healing outcomes, of High Purity Type-I Collagen Skin Substitute (HPTC) vs. Dehydrated Human Amnion / Chorion Membrane (dHACM) in the treatment of venous leg ulcers.

Sample Size Calculation

Standard Two-Sample Comparison of Proportions (e.g., wound closure rate)

Assuming:

- **α** = 0.05 (5%)
- **Power** = 0.80 (80%)
- **Proportion of success in control (p_1)** = 0.60 (typical healing rate for dHACM)
- **Proportion of success in treatment (p_2)** = 0.90 (expected improvement with Type-I collagen)

We use the formula for comparing two proportions:

n=(p1−p2)2(Zα/2+Zβ)2·[p1(1−p1)+p2(1−p2)]

Where:

- Zα/2Z_{\alpha/2}Zα/2 = 1.96 for α = 0.05
- ZβZ_{\beta}Zβ = 0.84 for 80% power

n=(1.96+0.84)2·[0.6(0.4)+0.9(0.1)](0.9−0.6)2=7.84·[0.24+0.09]0.09=7.84·0.330.09=2.590.09≈28.8n

We use the formula for comparing two proportions:

$$n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 \cdot [p_1(1-p_1) + p_2(1-p_2)]}{(p_1 - p_2)^2}$$

Where:

- $Z_{\alpha/2}$ = 1.96 for α = 0.05
- Z_{β} = 0.84 for 80% power

$$n = \frac{(1.96 + 0.84)^2 \cdot [0.6(0.4) + 0.9(0.1)]}{(0.9 - 0.6)^2} = \frac{7.84 \cdot [0.24 + 0.09]}{0.09} = \frac{7.84 \cdot 0.33}{0.09} = \frac{2.59}{0.09} \approx 28.8$$

~29 participants per group - 30 per group is statistically adequate to detect a difference from 60% to 90% healing rate with 80% power.

Randomization and Blinding: Patients were randomized 1:1 to the HPTC or dHCAM group using a computer-generated randomization sequence. Open-label design (patients and clinicians were aware of treatment allocation). Outcome assessors and statisticians were blinded.

Data Collection and Monitoring

a. Baseline data: Demographics, medical history, ulcer characteristics.
b. Weekly follow-ups: Wound measurements (photographic documentation), assess healing progress, pain scores, record adverse events and patient-reported outcomes.
c. Histopathological specimens were obtained at baseline and day 5 for vascularity assessment.
d. End-of-Study Visit (Week 6): final wound assessment, collect patient feedback on treatment experience, quality of life and scar assessment.
e. Data entry and monitoring was managed using an electronic data capture system.

Data Analysis: Data was analysed using SPSS v26.0. Continuous variables were expressed as mean± standard deviation, and categorical variables as frequencies and percentages. Student's t-test was used for comparing continuous variables between groups, and chi-square test for categorical variables. A p-value <0.05 was considered statistically significant. Kaplan-Meier survival analysis was used to assess time to complete healing and Cohen's d values for primary histopathological parameters.