

Study Limitations

This study has the following limitations: (1) a small sample size, which is inadequate for statistical analysis; (2) transplantation of TCD-51073 occurred in the absence of other concomitant therapies, so an add-on effect is unlikely to occur in the before-and-after comparisons; however, comparison with a group of untreated patients is necessary; (3) single-arm, open-label study, so the possibility of assessment bias cannot be ruled out; an independent analysis should be considered; and (4) the evaluation period of 26 weeks after transplantation is limited for demonstrating the efficacy of TCD-51073 in improving survival outcomes and preventing hospitalizations because of HF, thus requiring further mid- and long-term follow-up data.

Conclusions

This study demonstrated the feasibility and safety of the transplantation of TCD-51073 in patients with severe chronic HF due to ischemic heart disease, suggesting that TCD-51073 might maintain or improve cardiac function, symptoms, and physical function.

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Disclosures

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Supplementary Files

Supplementary File 1

Table S1. Inclusion and exclusion criteria for study of cell sheet transplantation

Table S2. Observation and test items and schedule of study of cell sheet transplantation

Figure S1. Serial change in B-type natriuretic peptide from baseline to 26 weeks after cell sheet transplantation.

Please find supplementary file(s);
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