JOURNAL OF WORLD SCIENCE
https://jws.rivierapublishing.id/index.php/jws
Volume 4 No. 9 September 2025
P-ISSN: 2828-8726
E-ISSN: 2828-9307

Advancements in Stem Cell Therapy for Pulmonary Fibrosis: A Comprehensive Review with Vinski Protocol

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ABSTRACT
Pulmonary fibrosis (FP) is a progressive interstitial lung disease with a poor prognosis and limited treatment options. Mesenchymal stem cell therapy (MSC) is emerging as a promising regenerative intervention. This comprehensive review aims to synthesize the current evidence regarding the safety and therapeutic benefits of MSC in FP, including observational findings from the Vinski Protocol.
This review analyzes clinical and observational studies in humans evaluating the administration of MSC for FP and related lung conditions. The synthesis of results shows that MSC therapy has a good safety profile in a variety of clinical trials, including in patients with idiopathic pulmonary fibrosis and post-COVID-19 lung injury. Trends in improved pulmonary outcomes and immunomodulatory effects were reported. Observational findings from the Vinski Protocol also support the regenerative potential of MSCs.
MSC therapy shows potential as a therapeutic modality for FP with acceptable safety. However, large-scale, long-term clinical trials are still needed to validate efficacy and standardize treatment protocols.

Keywords: Pulmonary fibrosis, stem cell therapy, mesenchymal stem cells, regenerative medicine, Vinski Protocol, clinical trial, immunomodulation.

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INTRODUCTION

Interstitial lung diseases contribute to significantly high mortality, morbidity, and healthcare-related financial burdens. Pulmonary fibrosis (PF) is particularly problematic. It is a progressive form of interstitial lung disease characterized by damage and scarring of lung tissue and a decline in lung function (Mei et al., 2022). Scarring causes lung tissue to thicken, ultimately compromising oxygen delivery (Mei et al., 2022). Idiopathic PF (IPF), the most common type of the disease, has an age-adjusted mortality rate of 5.4 per 100,000 persons with a median survival of 3–5 years (Mazurek et al., 2025). The disease has no cure. Treatment options for PF include medication, pulmonary rehabilitation, and respiratory support, primarily aimed at slowing disease progression (National Heart, Lung, and Blood Institute, 2022). While lung transplantation is also a treatment option, it carries significant risks of infection and rejection, and there is a shortage of donors (National Heart, Lung, and Blood Institute, 2022).

These limitations undermine the effectiveness of current treatment approaches, necessitating further research to develop more effective interventions (Lee et al., 2024; Wan et al., 2025).

Regenerative medicine has emerged as a potential solution for developing an effective treatment approach for PF. A particular focus of this intervention is stem cell therapy to repair damaged tissue and thus treat and prevent diseases such as PF (Cheng et al., 2022). The multipotency and immunogenicity of these cells allow their application to promote tissue regeneration in a targeted manner (Cheng et al., 2022). Accordingly, this research direction seeks to develop a stem cell therapy to facilitate lung tissue regeneration and ultimately alter the pathophysiology underlying PF. However, this research direction is relatively new despite its promise. Understanding the progress and challenges so far can inform further developments and future efforts to facilitate the process of developing an efficacious treatment. In that regard, this comprehensive review synthesizes current research on stem cell applications in PF, starting with PF pathophysiology and scientific foundations. It also explores the underlying mechanisms, evaluates clinical trial outcomes, and presents observational findings based on the Vinski Protocol at Celltech Stem Cell Centre. The findings reveal that although preliminary research using animal models suggests the effectiveness of stem cell therapy, there is a need for more large-scale trials with human participants because existing studies are scarce and include relatively small samples that undermine generalization (Chen et al., 2025; Fikry et al., 2025' Ikrama et al., 2024; Krentsis et al., 2024).

Therefore, the aim of this comprehensive review is to synthesize the latest evidence from clinical and observational studies in humans on the safety and efficacy of mesenchymal stem cell therapy (MSC) in the treatment of pulmonary fibrosis, including findings from the Vinski Protocol as supporting studies. The benefits of this study are expected to provide a comprehensive evidence-based foundation for clinicians, researchers, and policymakers in understanding the potential of stem cell therapy as a new therapeutic modality, as well as a foothold for designing more rigorous advanced-phase clinical trials to confirm efficacy and develop standard protocols for stem cell therapy for pulmonary fibrosis.

METHOD

This comprehensive review synthesizes findings from human clinical and observational studies investigating the application of mesenchymal stem cells (MSCs) in the treatment of pulmonary fibrosis (PF). The methodologies employed in these studies include structured clinical trials and qualitative observational research, each contributing essential insights into the safety, feasibility, and potential therapeutic effects of stem cell-based interventions.

Several clinical trials adopted rigorous research designs to evaluate both safety and preliminary efficacy:

1. Phase I trials, such as those conducted by Roesch et al. (2023) and Campo et al. (2021), primarily assessed the safety and tolerability of MSC infusion in adult patients with cystic fibrosis and idiopathic pulmonary fibrosis (IPF), respectively. These

studies employed dose-escalation models and follow-up assessments over 12 months using clinical evaluations and imaging.

2. Randomized controlled trials (RCTs)—notably by Shi, Huang, et al. (2021), Lanzoni et al. (2021), and Farkhad et al. (2022)—implemented double-blind and placebo-controlled protocols. These studies focused on patients with COVID-19-related lung injuries, investigating MSCs' effects on lung lesion reduction, inflammatory cytokine modulation, and patient survival outcomes. Though not exclusively targeting PF, the shared mechanisms of lung injury and repair lend relevance to PF therapy research.

Participant numbers varied across studies, ranging from 15 to over 100 individuals. Despite differing endpoints—such as lung lesion volume, walking distance, inflammatory biomarkers, and survival rates—all studies emphasized short-term safety while acknowledging the need for further trials with larger cohorts to confirm therapeutic efficacy.

Additionally, observational methodologies were applied at the Celltech Stem Cell Centre using the Vinski Protocol. A notable study by Vinski et al. (2024) employed a qualitative design involving two patients receiving quantum stem cell therapy for autoimmune conditions. Although not directly focused on PF, the study documented improvements in muscle strength, skin integrity, and inflammation, supporting the broader regenerative potential of stem cell therapy in chronic inflammatory conditions relevant to PF pathology.

Taken together, the methodological landscape reveals a human-centered approach to evaluating stem cell therapies—ranging from controlled clinical trials to early-stage observational studies—each forming a foundational step toward establishing MSC-based therapy as a viable treatment for pulmonary fibrosis.

RESULTS AND DISCUSSION

Roesch et al. (2023) conducted a phase I study to determine the safety and tolerability of MSCs therapy in cystic fibrosis (CF) of the lung. In particular, the phase I clinical trial aimed to evaluate a single intravenous infusion of allogeneic human mesenchymal stem cells (hMSCs) in adults with CF (Roesch et al., 2023). The research included 15 participants who received one of three escalating doses of hMSCs, which were derived from a healthy donor. They underwent close monitoring for 24 hours post-infusion (Roesch et al., 2023). The researchers also followed them for 12 months through clinic visits and phone calls (Roesch et al., 2023). The results indicated that hMSC infusion was safe and well-tolerated across all dosing groups (Roesch et al., 2023). Additionally, there were no dose-limiting toxicities, deaths, or serious infusion-related adverse events (Roesch et al., 2023). Most of the adverse events and serious adverse events were consistent with the underlying CF pathology (Roesch et al., 2023). Despite the positive outcome, the limited sample size and inability to consistently collect sputum samples undermined comprehensive efficacy evaluation. Nonetheless, this study showed that hMSC therapy is safe, which justified further trials to assess its therapeutic potential.

Shi, Huang, et al. (2021) also conducted a randomized, double-blind, placebo-controlled phase 2 trial aimed at assessing the safety and effectiveness of human umbilical cord-derived mesenchymal stem cells (UC-MSCs) in treating lung damage in severe COVID-19 patients. The study enrolled 101 patients, assigning them in a 2:1 ratio to receive either UC-MSCs or a placebo over three infusions on days 0, 3, and 6 (Shi, Huang et al., 2021). The primary outcome was the reduction in whole lung lesion volume by day 28, measured using a chest CT (Shi, Huang et al., 2021). While overall lung lesion reduction showed a positive trend in the UC-MSC group compared to placebo, the difference was not statistically significant (P=0.080) (Shi, Huang et al., 2021). However, there was a notable significant reduction in solid component lung lesions (P=0.043), albeit with a non-significant improvement in 6-minute walking distance (Shi, Huang et al., 2021). These findings lead the researchers to conclude that the treatment is safe and potentially effective. However, notable limitations of the study include the relatively small sample size. Larger phase 3 trials are necessary to evaluate long-term benefits and the mortality impact.

A separate phase I trial by Campo et al. (2021) produced different results. In this multicenter clinical trial, the researchers investigated the safety and feasibility of giving autologous bone marrow-derived mesenchymal stromal cells (BM-MSCs) through endobronchial infusion (Campo et al., 2021). The target population comprised patients with mild-to-moderate IPF (Campo et al., 2021). Accordingly, 17 patients had their bone marrow harvested, while 13 received BM-MSCs (Campo et al., 2021). The researchers excluded participants with chromosomal abnormalities and those who died before treatment. Patients received one of three increasing doses, and monitoring ensued for 12 months using pulmonary function tests, imaging, and symptom assessments (Campo et al., 2021). The results showed that the patients tolerated the procedure generally well, as there were no severe side effects from the infusion (Campo et al., 2021). However, disease progression occurred in some participants; 2 patients died due to the disease, and 1 needed a lung transplant; only 3 participants showed stable function at 12 months (Campo et al., 2021). Besides, a significant number of cultured BM-MSCs showed genomic instability, raising concerns about using autologous cells in this group (Campo et al., 2021). Thus, the treatment had a good safety profile. However, the limited effectiveness, high rate of disease progression, and genetic issues in MSCs indicate some challenges for future therapeutic use.

Moreover, Lanzoni et al. (2021) carried out a double-blind, phase 1/2a randomized controlled trial investigating the safety and potential effectiveness of UC-MSCs in treating acute respiratory distress syndrome (ARDS) caused by COVID-19. While this study did not focus exclusively on PF, the paracrine signaling and inflammatory modulation aspects are involved, making it highly relevant. The study included 24 hospitalized patients who were randomly assigned to receive either two intravenous infusions of UC-MSCs or a placebo 72 hours apart, alongside standard care (Lanzoni et al., 2021). The main aim of the researchers was to assess treatment safety, while secondary endpoints were survival, time to recovery, and inflammation levels (Lanzoni et al., 2021). The outcome analysis showed that the UC-

MSC group experienced significantly fewer serious adverse events, 2 compared to 16, and had markedly better survival at 91% versus 42% and faster recovery times compared to the control group (Lanzoni et al., 2021). There was also a notable reduction in inflammatory cytokines, including IL-6 and TNF-α, in the UC-MSC group, indicating a modulation of the cytokine storm characteristic of severe COVID-19 (Lanzoni et al., 2021). This finding is highly relevant for PF due to the role of these cytokines in the disease's pathophysiology. The researchers also found that there were no adverse reactions related to UC-MSC infusions (Lanzoni et al., 2021). Despite promising results, the study also had a small sample size. This recurrent limitation emphasizes the need for larger trials to validate these findings.

Farkhad et al. (2022) also explored COVID-19-related ARDS and had findings similar to those of Lanzoni et al. (2021). While this research did not exclusively focus on PF, the related pathophysiology provides relevance. The single-center, phase 1 clinical trial assessed the safety and potential benefits of UC-MSCs in patients with mild to moderate COVID-19-induced ARDS (Farkhad et al., 2022). The researchers included 20 participants, dividing them into two groups: one received standard care, and the other received standard care plus three intravenous doses of UC-MSCs (Farkhad et al., 2022). Over a 17-day follow-up period, the researchers monitored respiratory function, C-reactive protein (CRP) levels, and inflammatory and anti-inflammatory cytokines (Farkhad et al., 2022). The study showed that there were no serious adverse effects from UC-MSC administration, except for mild headaches, the most common side effect (Farkhad et al., 2022). The intervention group had significant improvements in oxygenation, greater reductions in CRP and pro-inflammatory cytokines, including IL-6, TNF-α, IFN-γ, and IL-17A, and increased levels of anti-inflammatory markers such as IL-10 and TGF-β (Farkhad et al., 2022). These findings point to the immunomodulatory mechanism and potential effectiveness in PF treatment. Still, this study also had a small sample size and short follow-up period, which warrants larger and longer-term studies.

Observational Findings: The Vinski Protocol at Celltech Stem Cell Centre

Recent experimental studies from the Celltech Stem Center applying the Vinski protocol to PF treatment using MSCs are scarce. The center has yet to publish publicly available studies or outcomes focusing on this particular application of regenerative medicine. Nonetheless, the Celltech Stem Center has conducted studies on stem cell use, providing observations that inform progress in research pertaining to PF. Vinski et al. (2025) observe that gene therapy is a pivotal tool in regenerative medicine because it can provide targeted and sustained expression of therapeutic genes, thereby repairing or replacing damaged tissues.

The researchers also observed that stem cells, scaffolds, and biomaterials significantly enhanced gene delivery and tissue regeneration (Vinski et al., 2025). This aspect is evident in the case of PF, where studies emphasize the role of MSCs in alveolar epithelial cell regeneration. Vinski et al. (2025) also note that gene therapy enhances the repair mechanisms of the body regardless of whether it is used in vivo or ex vivo. In another study, Vinski et al.

(2024) conducted a qualitative study to explore the application and efficacy of quantum stem cell therapy. Although the research focused on autoimmune diseases, including only 2 participants, its findings relate closely to the aspects targeting PF therapy: tissue regeneration (Vinski et al., 2024). Notable findings pertaining to both participants included improved muscle strength and skin health, including improved soft tissue and reduced inflammation, all of which implicate the intervention's effect on tissue repair. The researchers note that the stem cells could achieve the effects due to their ability to activate regeneration and homing to tissues requiring repair (Vinski et al., 2024). Overall, the researchers emphasize the potential of stem cell therapy in regenerative medicine. By using cells such as MSCs to promote healing, researchers and care providers can develop effective therapeutic options for problematic conditions such as PF.

CONCLUSION

While preliminary human studies show promising safety outcomes for stem cell therapy in PF treatment, more extensive clinical trials involving larger cohorts are necessary to confirm long-term efficacy and therapeutic impact. Current research is limited and often based on small sample sizes, making it difficult to draw broad, reliable conclusions on the efficacy, safety, and long-term impact of this intervention. This research direction is pertinent because PF has low survival rates since existing treatments only slow disease progression, and lung donors are scarce. Stem cell therapy, particularly using MSCs, shows the most notable promise of therapeutic applications. Current research shows that these cells can promote lung healing through paracrine signaling, immunomodulation of immune response, epithelial repair and differentiation, and homing. The reviewed animal experiments show effectiveness, and human trials suggest that the approach is safe, with only one showing no significant outcomes. Therefore, these findings provide a foundation to explore this intervention further, especially emphasizing addressing the limitations of using small sample sizes. There is a need for more studies that include more human participants to confirm previous research and provide an effective therapeutic approach for PF patients.

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