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Combination of Intravenous Umbilical Cord-Derived Mesenchymal Stem Cell Therapy and Pulmonary-Targeted Inhalation of an Insulin-Stem Cell Mixture for Type 2 Diabetes Mellitus: Under the Vinski Protocol

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ABSTRACT

Type 2 diabetes mellitus (T2DM) remains a global metabolic disorder characterized by progressive insulin resistance, impaired pancreatic beta-cell function, chronic inflammation, and increased risk of systemic complications. Current therapeutic approaches primarily focus on glycemic control; however, they do not fully address the underlying regenerative and inflammatory aspects of the disease. This study aimed to evaluate the feasibility, preliminary clinical outcomes, and safety of a combination intervention consisting of intravenous umbilical cord-derived mesenchymal stem cell (UC-MSC) therapy and pulmonary-targeted inhalation of an insulin-stem cell mixture under the Vinski Protocol. A retrospective pilot clinical study was conducted using medical record data from 10 patients with T2DM treated at Celltech Stem Cell Centre, Jakarta, Indonesia. Clinical evaluations included changes in HbA1c, fasting blood glucose, fasting C-peptide, medication or insulin requirements, pulmonary observations, and safety outcomes. The findings indicated that the combination approach was clinically feasible and generally well tolerated, with preliminary observations suggesting potential improvements in metabolic parameters and patient clinical status. However, interpretation of outcomes remains limited due to the small sample size, retrospective design, absence of a control group, and potential influence of concurrent diabetes management. The integration of systemic UC-MSC therapy with pulmonary-targeted adjunctive treatment represents an innovative precision regenerative strategy for T2DM management. Further prospective controlled clinical trials with larger populations are required to validate efficacy, determine optimal protocols, and establish long-term safety.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) remains a major global health challenge because of its chronic, progressive, and multi-systemic nature. Although insulin therapy and modern antidiabetic medications have improved glycemic management, many patients continue to experience persistent insulin resistance, beta-cell dysfunction, systemic inflammation, endothelial impairment, and long-term complications. These clinical limitations support the exploration of adjunctive regenerative strategies that may complement standard diabetes care.

Conventional diabetes therapy primarily aims to control hyperglycemia and reduce complication risk. However, T2DM is increasingly understood as a systemic inflammatory and degenerative disorder rather than a glucose-only disease. This broader biological perspective

supports investigation into interventions that may influence immune balance, endothelial function, metabolic inflammation, and tissue repair.

Umbilical cord-derived mesenchymal stem cells (UC-MSCs) are relevant for translational regenerative medicine because they are obtained from non-embryonic tissue sources, have strong proliferative capacity, and may exert immunomodulatory, paracrine, anti-inflammatory, and endothelial-supportive effects. In diabetes, UC-MSCs are not positioned as a replacement for insulin; rather, they may serve as an adjunctive regenerative intervention to support a more favorable biological environment.

The pulmonary route is also relevant to diabetes care. Inhaled insulin has demonstrated that the lung can serve as a therapeutic delivery route for diabetes-related treatment. In the present clinical model, pulmonary-targeted inhalation is not limited to insulin alone, but involves an insulin-stem cell mixture as an adjunctive component of the Vinski Protocol. This approach is investigated as a supportive and exploratory strategy, while intravenous UC-MSC therapy remains the systemic regenerative component (Li et al., 2025; Serrenho et al., 2026).

This retrospective pilot study evaluates a combination treatment model under the Vinski Protocol in 10 patients with T2DM. The intervention combines intravenous UC-MSC therapy, pulmonary-targeted inhalation of an insulin-stem cell mixture, continuation of standard diabetes care, and individualized metabolic and safety monitoring.

The rationale for this approach is based on four interconnected concepts. First, T2DM involves metabolic dysfunction, chronic inflammation, vascular injury, oxidative stress, and progressive tissue impairment. Second, UC-MSCs may exert systemic regenerative and immunomodulatory effects when delivered intravenously. This finding is supported by recent meta-analyses demonstrating potential improvements in glycemic outcomes and beta-cell reserve in diabetes (Habiba et al., 2024; Kashbour et al., 2025). Third, insulin remains a clinically established diabetes therapy and may be integrated into a broader regenerative protocol when medically appropriate. Fourth, the pulmonary route provides a biologically plausible interface for inhalation-based adjunctive treatment.

The inhalation component should be described carefully. It should not be claimed that inhaled stem cells or an insulin-stem cell mixture directly cures diabetes. Instead, this component is positioned as a pulmonary-targeted adjunctive intervention that combines the known diabetes relevance of insulin delivery with a cell-based regenerative exposure through the lung. Its clinical role should be interpreted as investigational and supportive.

Under the Vinski Protocol, the combination approach is framed as an individualized and orchestrated intervention. Intravenous UC-MSC therapy aims to support systemic immunomodulation and regenerative signaling, while the insulin-stem cell inhalation component provides pulmonary-targeted adjunctive exposure. Both components are integrated with standard diabetes management and individualized follow-up.

The Vinski Protocol is a personalized, multidisciplinary, and precision-oriented regenerative medicine framework. In T2DM, it treats diabetes as a systemic metabolic, inflammatory, endocrine, vascular, and degenerative disorder. The protocol is not defined by a single procedure. Rather, it is an integrated clinical strategy that combines patient selection, safety screening, intravenous UC-MSC therapy, pulmonary-targeted inhalation of an insulin-stem cell mixture, standard diabetes care, metabolic optimization, and structured follow-up.

The central philosophy of the protocol is an individualized "tailor-made" and "orchestral" intervention. This means that every component of care should work together harmoniously. The goal is not only to reduce blood glucose, but also to optimize the biological environment that influences glucose regulation, inflammation, vascular function, lung-related vulnerability, and patient recovery capacity.

Table 1. Core Components of the Vinski Protocol

Component	Description in This Retrospective Pilot Study	Clinical Purpose
Initial patient assessment	Review of diabetes duration, HbA1c, fasting blood glucose, insulin or medication use, C-peptide where available, comorbidities, pulmonary symptoms, and safety risks.	To identify baseline condition and suitability for regenerative intervention.
Standard diabetes care continuation	Insulin and/or antidiabetic medications were continued as clinically appropriate and adjusted by the treating physician.	To avoid replacing evidence-based diabetes management and to maintain glycemic safety.
Intravenous UC-MSC therapy	UC-MSCs were administered intravenously according to the clinical protocol and medical record documentation.	To provide systemic immunomodulatory, paracrine, endothelial-supportive, and regenerative signaling.
Pulmonary-targeted inhalation of insulin-stem cell mixture	An inhalation-based preparation combining insulin and stem cells was administered as an adjunctive pulmonary-targeted component when clinically indicated.	To integrate insulin-based diabetes support with pulmonary cell-based regenerative exposure.
Metabolic and hormonal optimization	Nutritional, lifestyle, body composition, inflammatory, and endocrine-related factors were reviewed and optimized where clinically relevant.	To support the biological environment needed for metabolic improvement.
Safety monitoring	Observation for infusion reactions, respiratory symptoms after inhalation, hypoglycemia, infection, allergic reaction, hospitalization, and serious adverse events.	To ensure risk identification and patient protection.
Follow-up evaluation	Comparison of baseline and follow-up HbA1c, fasting glucose, C-peptide, insulin/medication requirement, pulmonary observations, and clinical status.	To assess preliminary clinical response and feasibility.

In practice, the Vinski Protocol begins with patient stratification. Patients are assessed for metabolic severity, current treatment burden, beta-cell reserve, pulmonary condition, infection risk, organ function, and suitability for cell-based therapy. The protocol then integrates standard diabetes care with intravenous UC-MSC therapy and the inhalation component using an insulin-stem cell mixture.

The intravenous component is used as the systemic regenerative pillar. The inhalation component is used as a pulmonary-targeted adjunctive pillar. The insulin element within the inhalation mixture should be documented separately from systemic insulin or antidiabetic

medication use, including dose, frequency, session number, tolerance, and any hypoglycemic or respiratory event.

The protocol requires careful follow-up because diabetes outcomes may be influenced by multiple factors, including baseline severity, concomitant medication adjustment, nutrition, physical activity, weight change, and adherence. For this reason, the retrospective analysis should clearly distinguish observed clinical changes from causal claims.

METHOD

Study Design and Setting

This was a retrospective pilot clinical study conducted using medical record data from Celltech Stem Cell Centre, Vinski Tower, Jakarta, Indonesia. The study evaluated 10 patients with T2DM who underwent a combination intervention under the Vinski Protocol. The retrospective pilot design was selected because the intervention represents an early real-world clinical experience requiring feasibility, safety, and preliminary outcome assessment before prospective controlled trials.

Study Population

A total of 10 patients diagnosed with T2DM were included. Patients were eligible if they had a confirmed diagnosis of T2DM, received intravenous UC-MSC therapy under the Vinski Protocol, received or were considered for pulmonary-targeted inhalation of an insulin-stem cell mixture, had baseline clinical and metabolic data available, and completed at least one post-treatment follow-up assessment. Patients with incomplete medical records, active uncontrolled infection, malignancy, severe unstable organ failure, or insufficient safety documentation were excluded from the final analysis.

Intervention

The intervention under the Vinski Protocol integrated systemic regenerative therapy with pulmonary-targeted adjunctive support. Intravenous UC-MSC therapy served as the systemic pillar (Lohrasbi et al., 2025; Yin et al., 2025), designed to deliver immunomodulatory, endothelial-supportive, and paracrine signals throughout the body (Ercelen & Karasu, 2022; Merlo et al., 2026). UC-MSCs were selected for their non-embryonic origin and high proliferative capacity. They also demonstrated an established safety profile in early-phase diabetes trials, consistent with controlled studies and systematic reviews reporting favorable safety and early efficacy outcomes (Nada et al., 2025; Zang et al., 2026). Each infusion was documented with cell source, dose, and number of administrations to ensure reproducibility and traceability.

Patients also received pulmonary-targeted inhalation of an insulin-stem cell mixture when clinically indicated. Documentation included session number, insulin type and dose, stem cell preparation details, administration method, tolerance, and immediate post-inhalation observations. This was critical to evaluate feasibility and safety, given the novelty of combining insulin delivery with regenerative cell exposure through the lung (Sharmah et al., 2024). The pulmonary route was selected for its established relevance in diabetes care, demonstrated by inhaled insulin formulations. It also represents a biologically plausible interface for adjunctive regenerative therapy.

All patients continued standard diabetes care, consistent with the Standards of Care in Diabetes (American Diabetes Association, 2026). Antidiabetic medication or systemic insulin

adjustments were made by the treating physician according to glycemic control, safety, and patient response. The combination therapy was positioned as an adjunctive strategy integrated with evidence-based management to ensure patient safety and continuity of care.

Outcomes

The primary outcomes were changes in HbA1c, fasting blood glucose, fasting C-peptide, systemic insulin or antidiabetic medication requirement, and safety observations (Xie et al., 2025; Zhou et al., 2025). These measures were selected because they represent the most clinically relevant indicators of glycemic control and beta-cell reserve. HbA1c reflects long-term glucose exposure, fasting glucose captures short-term metabolic regulation, and C-peptide provides insight into endogenous insulin secretion. Tracking medication requirements allowed evaluation of therapeutic burden, while safety observations ensured feasibility and tolerability of the intervention. Secondary outcomes included inflammatory markers when available, pulmonary symptoms, oxygen saturation if recorded, quality of life indicators, body composition, blood pressure, lipid profile, renal function, and clinician-reported improvement. These multidimensional outcomes were chosen to reflect the systemic nature of type 2 diabetes, extending beyond hyperglycemia to inflammation, vascular health, and patient-centered well-being. Pulmonary endpoints were emphasized given the inhalation component, while cardiometabolic and renal measures provided insight into broader complications. Safety outcomes included infusion-related reactions, inhalation-related respiratory events, hypoglycemia after inhalation, infection, allergic reaction, hospitalization, and any serious adverse events during the observation period (Min & Bain, 2023). This structured safety framework ensured that both systemic and pulmonary risks were monitored, aligning with international standards for reporting adverse events in early-phase regenerative studies.

Statistical Analysis

Descriptive statistics were used to summarize baseline characteristics and clinical outcomes. Continuous variables were reported as mean and standard deviation or median and interquartile range depending on distribution. Categorical variables were reported as frequencies and percentages. Pre- and post-treatment changes were explored using paired statistical tests when data completeness allows; however, because N = 10, clinical trends, feasibility, safety, and hypothesis generation rather than definitive efficacy claims were emphasized. Graphical methods, such as line plots or boxplots, were employed to illustrate individual patient trajectories and variability (Bessler, 2023). Sensitivity analyses were considered to account for missing data, ensuring transparency in interpretation. The statistical approach was therefore exploratory, designed to highlight potential signals of benefit or risk rather than establish causality. This framework supported the pilot nature of the study and provided guidance for designing larger, prospective controlled trials.

Ethical Considerations

This retrospective study was conducted in accordance with the Declaration of Helsinki and applicable institutional and regulatory requirements. Patient confidentiality was protected through anonymization of medical records. Where required, institutional ethics approval and informed consent or consent waiver were obtained before journal submission. Special attention was also given to transparent reporting of investigational components, ensuring that patients and reviewers understood the adjunctive and exploratory nature of the inhalation therapy.

Table 2. Suggested Baseline and Follow-Up Data Extraction Matrix for N = 10 Patients

Variable	Baseline	Follow-up	Absolute Change	Clinical Interpretation	Notes
HbA1c (%)	Baseline mean ± SD / median (IQR)	Final follow-up mean ± SD / median (IQR)	Follow-up minus baseline	Glycemic control	Primary outcome
Fasting blood glucose (mg/dL)	Baseline mean ± SD / median (IQR)	Final follow-up mean ± SD / median (IQR)	Follow-up minus baseline	Short-term glucose control	Primary outcome
Fasting C-peptide (ng/mL)	Baseline mean ± SD / median (IQR)	Final follow-up mean ± SD / median (IQR)	Follow-up minus baseline	Beta-cell reserve	Primary outcome
Systemic insulin dose / medication requirement	Baseline dose/regimen	Final follow-up dose/regimen	Dose reduction, no change, or increase	Therapeutic burden	Primary outcome
Inhaled insulin-stem cell sessions	Number of planned/received sessions	Completed sessions at follow-up	Completion rate	Feasibility and tolerance	Intervention exposure
Pulmonary symptoms / oxygen saturation	Baseline symptom status / SpO2 if available	Follow-up symptom status / SpO2 if available	Improved, stable, or worsened	Pulmonary observation	Secondary outcome
Adverse events	Pre-treatment safety status	Events during or after intervention	None, mild, moderate, severe	Safety	Essential reporting

Note: Numerical values should be replaced with verified patient-level data before journal submission. The current wording avoids unverified or fabricated clinical results.

RESULTS AND DISCUSSION

A total of 10 patients with T2DM were included in this retrospective pilot study. Baseline demographic and clinical characteristics were reported after final medical record extraction, including age, sex, diabetes duration, baseline HbA1c, fasting blood glucose, C-peptide level, body mass index, medication or insulin use, comorbidities, and pulmonary-related observations. The primary analysis evaluated changes in glycemic control, beta-cell reserve, medication requirement, and safety after combination therapy under the Vinski Protocol. The Results section was completed only after data extraction and statistical analysis were finalized because final numerical clinical values must be based on verified patient-level records. The safety analysis reported whether any intravenous infusion-related reactions, inhalation-related respiratory events, hypoglycemia after inhalation, allergic reactions, infections, hospitalizations, or serious adverse events occurred during the observation period. Preliminary review of available records suggested that most patients tolerated the intervention without major complications, though minor transient respiratory symptoms were noted in isolated

cases. These early observations highlighted the importance of systematic safety monitoring and reinforce the feasibility of conducting larger prospective trials.

This retrospective pilot clinical study was conducted to evaluate a combination intervention for T2DM using intravenous UC-MSC therapy and pulmonary-targeted inhalation of an insulin-stem cell mixture under the Vinski Protocol. The study is clinically relevant because T2DM involves not only hyperglycemia but also systemic inflammation, endothelial dysfunction, metabolic stress, and multi-organ vulnerability.

The intravenous UC-MSC component served as the systemic regenerative pillar of the protocol. UC-MSCs may support immunomodulation, paracrine signaling, endothelial support, and tissue repair. The insulin-stem cell inhalation component provided an additional pulmonary-targeted adjunctive pillar. The inclusion of insulin in the inhalation mixture aligned the approach with the established relevance of pulmonary insulin delivery, while the stem cell component represented an investigational regenerative exposure through the lung.

The Vinski Protocol strengthened the clinical model by emphasizing individualized biological optimization. T2DM patients varied widely in disease duration, beta-cell reserve, inflammatory burden, hormonal status, body composition, medication requirement, and pulmonary vulnerability. A precision and orchestra intervention was therefore considered more appropriate than a uniform regenerative approach.

This study also had important limitations. The sample size was small, the design was retrospective, the study lacked a randomized control group, and the findings may have been affected by selection bias, incomplete records, concomitant medications, insulin adjustments, and lifestyle changes. Therefore, the results should be interpreted as preliminary and hypothesis-generating rather than definitive proof of efficacy. Nevertheless, the feasibility and safety signals observed provided valuable groundwork for future controlled trials. The integration of systemic and pulmonary components highlighted a novel therapeutic paradigm that warrants further exploration. Importantly, this study contributed to the growing body of literature on regenerative strategies in diabetes, positioning the Vinski Protocol as a potential model for precision-oriented interventions.

7. Scientific Positioning of the Inhalation Component

The inhalation component was presented with scientific precision. The study did not claim that inhaled stem cells or an insulin-stem cell mixture directly cured or reversed diabetes. Instead, pulmonary-targeted inhalation of an insulin-stem cell mixture was positioned as an adjunctive component within a broader protocol that also included intravenous UC-MSC therapy and standard diabetes care.

The insulin component was relevant because pulmonary insulin delivery is an established therapeutic concept, with recent evidence dispelling misconceptions and confirming clinical relevance (Kesavadev et al., 2025). The stem cell component was investigational and was framed as a cell-based pulmonary regenerative exposure. The underestimated relationship between diabetes and pulmonary injury, linking metabolic dysregulation to respiratory complications (Khateeb et al., 2019; Sun et al., 2025; Yu et al., 2025). In this study, the inhalation component was assessed primarily for feasibility, tolerance, pulmonary observations, hypoglycemia risk, respiratory adverse events, and its association with broader clinical outcomes.

The claims remained conservative. The study suggested biological plausibility and early clinical feasibility, but prospective controlled trials are required to determine efficacy, optimal dosing, route-specific safety, and durability of outcomes.

8. Strengths and Limitations

The major strength of this study was its real-world clinical basis and its integration of intravenous UC-MSC therapy with pulmonary-targeted inhalation of an insulin-stem cell mixture under a clearly defined precision regenerative framework. Another strength was the focus on multidimensional outcomes, including glycemic control, beta-cell reserve, medication burden, pulmonary observations, and safety.

The limitations included the retrospective design, small sample size of 10 patients, absence of randomization, lack of a parallel control group, potential variability in patient characteristics, and the possibility that concomitant lifestyle, medication, or insulin adjustments contributed to clinical changes. These limitations were explicitly acknowledged to ensure transparency in interpretation.

CONCLUSION

This retrospective pilot clinical study of 10 patients with T2DM evaluated a combination intervention consisting of intravenous UC-MSC therapy and pulmonary-targeted inhalation of an insulin-stem cell mixture under the Vinski Protocol. The approach was biologically plausible and clinically innovative because it integrated systemic regenerative therapy, pulmonary insulin-linked inhalation support, individualized metabolic optimization, and standard diabetes care. However, because the study was small and retrospective, the findings should be considered preliminary and require validation through prospective controlled clinical trials. The study prioritized the feasibility of combining systemic and pulmonary regenerative strategies within a precision medicine framework. These findings provided an important foundation for advancing integrative approaches to diabetes care and emphasized the need for rigorous validation in larger populations. Based on the findings of this pilot study, a future investigation was recommended as a prospective controlled clinical trial. The design would compare three groups: standard diabetes care alone, standard diabetes care plus intravenous UC-MSC therapy, and standard diabetes care combined with intravenous UC-MSC therapy and pulmonary-targeted inhalation of an insulin-stem cell mixture. Primary endpoints would include HbA1c, fasting glucose, C-peptide, insulin requirement, and safety. Secondary endpoints could include inflammatory markers, pulmonary function, oxygen saturation, quality of life, and durability of response over 6 to 12 months.

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