DestroCell

Placenta-Derived Decidua Stromal Cells

DestroCell: A New Frontier in GvHD Treatment

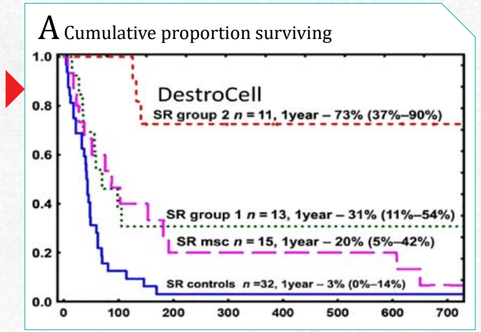
TASKIN BioRegeneration | دسترو سل DestroCell

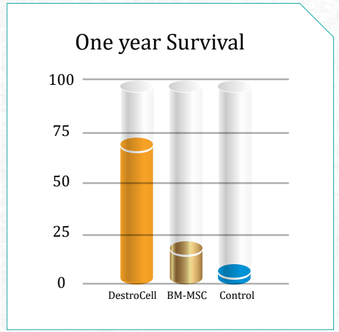
DestroCell significantly alleviates GvHD symptoms while ensuring a safety profile with no severe adverse events.

DestroCell for steroid refractory acute GvHD (SR-aGvHD), offering hope for a brighter future.

Clinical Efficay

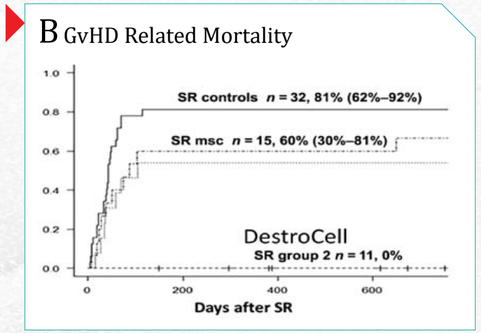
Kaplan-Meier estimates of overall survival for patients with SR-aGvHD treated with decidua stromal cells versus controls showed that patients in SR Group 2, treated with DestroCell, had a significantly higher survival rate compared to SR Group 1 (p = .02), SR BM-MSC-treated patients (p = 0.015), and SR controls (p < .001).

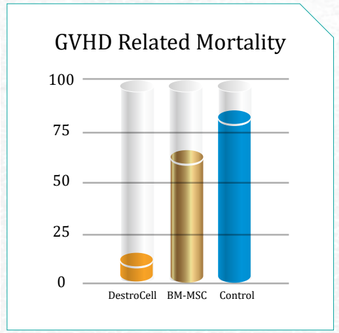




B) The relative risk of experiencing GvHD symptoms at the time of death was significantly higher in SR group 1, SR msc (BM-MSC treated patients), and SR controls compared to SR group 2 (DestroCell-treated patients) (p < 0.01; p < 0.01; and p < 0.001, respectively).

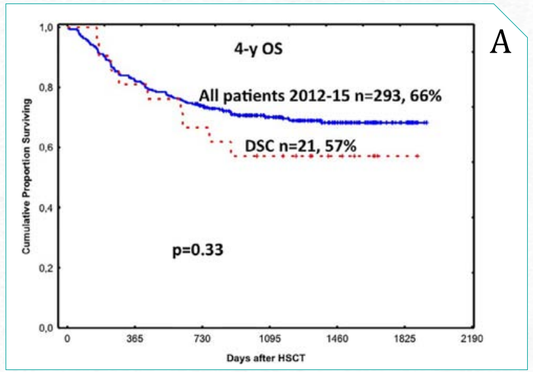
Note:
Group 1 consists of 13 patients who received thawed DSCs infused in a buffer supplemented with AB plasma. Group 2 includes 11 patients who received thawed DSCs (DestroCell) infused in a buffer supplemented with albumin. These groups are represented on the side graphs.





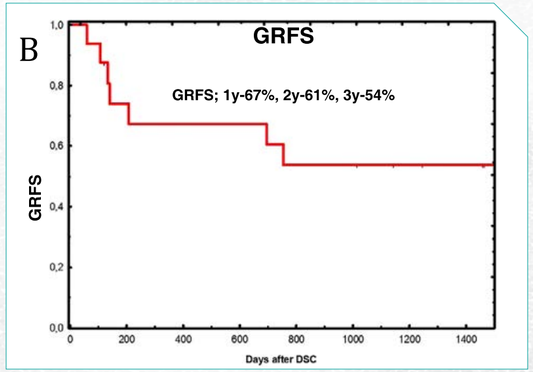
Ringden O, et al. Stem Cells Translational Medicine, 2018.

Long-term Follow-up of SR-GvHD Patients

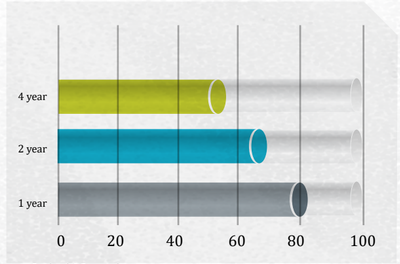


A) Four-year overall survival in all patients who underwent HSCT at the Center for Allogeneic Stem Cell Transplantation, Karolinska Institute, Huddinge Hospital, between 2012 and 2015, and in 21 patients treated with DSCs (DestroCell) for severe acute GVHD.

B) Probability of graft-versus-host disease-free relapse-free survival (GRFS) in all 21 patients from the time of DSC (DestroCell) treatment.



Long-term Survival of SR-GvHD Patients



Sadeghi B, et al. Biol Blood Marrow Transplant, 2019.

DestroCell Vs BM-MSC

	DestroCell	BM-MSCs
Tissue Origin	Placenta & Fetal Membranes	Bone Marrow
Differentiation to Fat and Cartilage	+/-	+++
Size, Volume	2400 fl	4600 fl
Expansion Potential	+++	+
PD-L1, PD-L2 Expression	+++	+/-
Needs IFN-γ Licensing for Activation	-	++
Inhibition of Lymphocyte Proliferation (MLR)	+++	+
Induction of Regulatory T Cells Frequency	++	+

1. Sadeghi B, et al. Cytotherapy, 2023.
2. Karlsson H, et al. Translational Immunology, 2012.
3. Erkers T, et al. , Stem cells and Development, 2013.

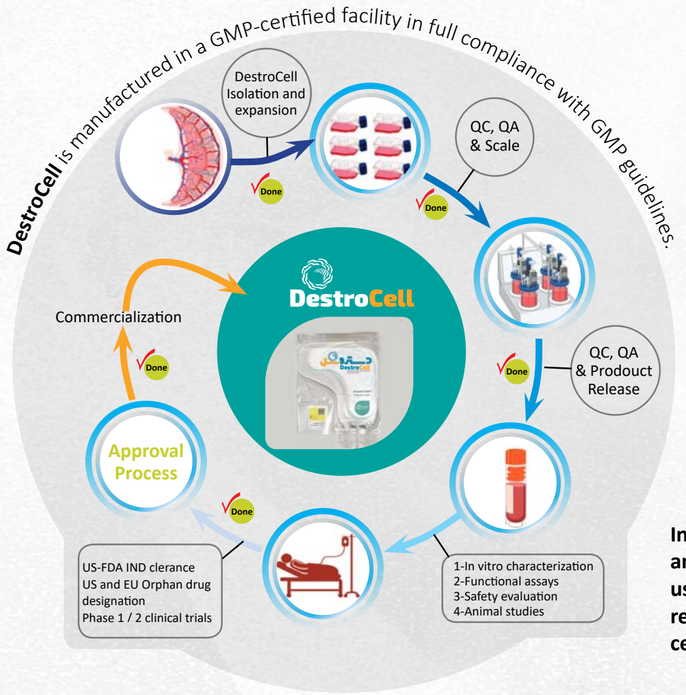
DestroCell has superior immune tolerance induction and immunomodulatory function in experimental seting and clinical application

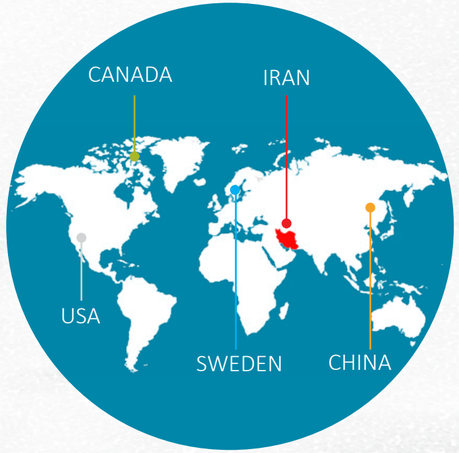
DestroCell Vs Ruxolitinib

	Ruxolitinib	Best Availbe Therapy	DestroCell
Overal Response rate (ORR) at 4 weeks	62%[1]	39%[1]	100%[2]
(CR+PR)	(34%+28%)	(19%+20%)	(52%+48%)
Durable ORR at 8 weeks	40%[1]	22%[1]	100%[2]
One year Survival	50%[1]	45%[1]	76%[2]
Treatment discountinuation (TD)	72%[1]	85%[1]	0%[2]
TD due to Lack of efficacy	21%[1]	44%[1]	0%[2]
Any Advers Events (AEs)	95%[1]	93%[1]	0%[2]
Dose Modification due to AEs at day 28	38%[1]	9%[1]	0%[2]

1. Zeiser R, et al. N Engl J Med, 2020.
2. Ringden O, et al. Stem Cells Translational Medicine, 2018.

Producton Process





Independent clinical studies in Sweden, Iran, and Canada show similar, successful outcomes using locally produced DSC, emphasizing the reproducibility and confirmed effectiveness of the cell therapy protocol.

Highlights of Prescribing Information

These highlights do not include all the information necessary for the safe and effective use of DestroCell. For full details, please refer to the complete prescribing information.

Overview and Safety Information

DestroCell has demonstrated a favorable safety profile in clinical studies, with no serious adverse effects reported. A small number of patients experienced mild symptoms, such as dizziness, headache, and increased heart rate, which resolved without medical intervention. Concurrent use with infliximab is contraindicated due to potential drug interactions.

Indications and Usage

DestroCell is a cell therapy product derived from placenta-based decidua stromal cells, indicated for the treatment of patients with steroid-refractory graft-versus-host disease (GvHD).

Administration Guidelines

- Intravenous Infusion Only: Verify that the patient's identity matches the information on the infusion bag before administration.
- **Premedication:** Use hydrocortisone and chloramphenicol as premedication.
- **Supervision:** Administration should occur in a medical center capable of emergency interventions, under a physician's supervision.

Dosage and Formulation

- **Dosage Form:** DestroCell is provided as a cell suspension for intravenous infusion.
- **Dosage:** Recommended dose is 1 ± 0.2 × 10^6 cells per kilogram of body weight.
- **Composition:** Each infusion bag contains the appropriate number of placenta-derived decidua stromal cells, diluted in 40 mL of physiological saline and 5% human albumin.
- **Contraindications:**

DestroCell should not be used in:

- Patients with known allergies to cell therapy or any component of the product.
- Patients with advanced-stage cancer.
- Individuals with thrombophlebitis or severe coagulopathy.
- Patients with extensive fungal infections involving multiple organs.

Precautions And Monitoring

- **Restricted Use:** Intended for cases where steroid therapy has not provided adequate therapeutic response.
- **Monitoring:** Continuously observe the patient's condition during and after cell infusion, with particular attention to respiratory status, vital signs, arterial oxygen saturation, and other relevant clinical parameters.

Adverse Reactions

While no serious adverse reactions have been observed in clinical use, potential but uncommon effects may include thrombophlebitis and pulmonary embolism, based on theoretical considerations.

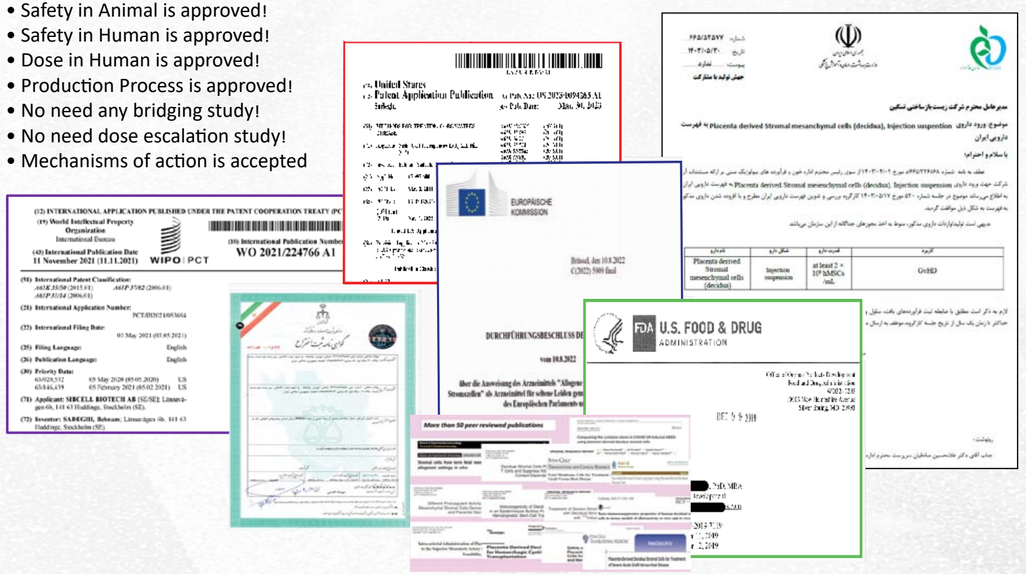
Reporting Adverse Reactions

To report any suspected adverse reactions, contact TASKIN BioRegeneration at +989029220385.

Achievements

Successful clinical and toxicological studies conducted at the Karolinska Institute led by Prof. Olle Ringden and Dr. Behnam Sadeghi, 2009-present
DestroCell project received orphan drug designation from the US FDA in 2019 & EMMA in 2022
DestroCell obtained US and World Patent for the treatment of ARDS/Covid in 2023
DestroCell obtained IND approval from the FDA, 2022 which means:

- Safety in Animal is approved!
- Safety in Human is approved!
- Dose in Human is approved!
- Production Process is approved!
- No need any bridging study!
- No need dose escalation study!
- Mechanisms of action is accepted



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