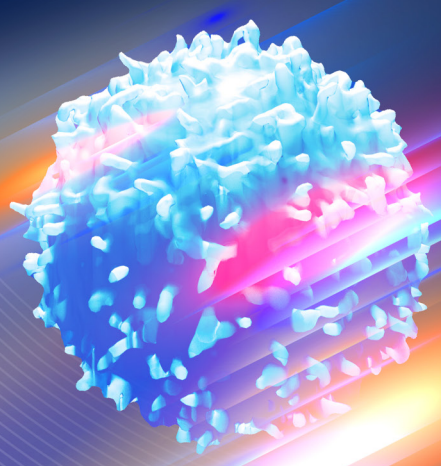


DestroCell

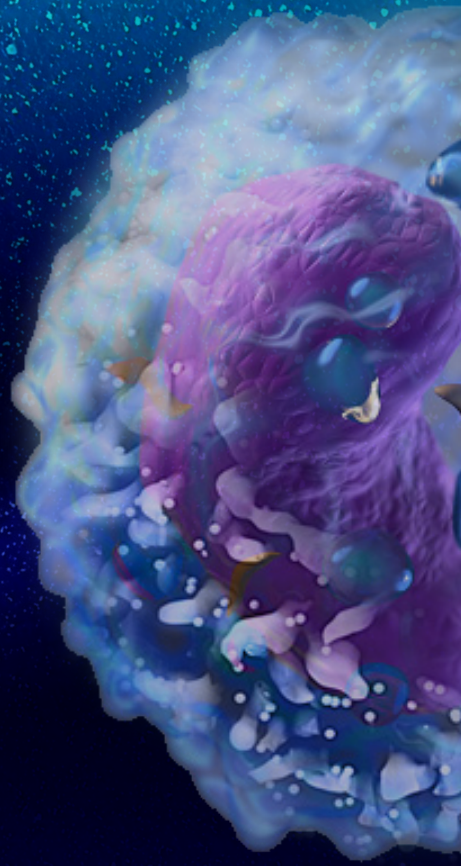
Placenta-Derived Decidua Stromal Cells

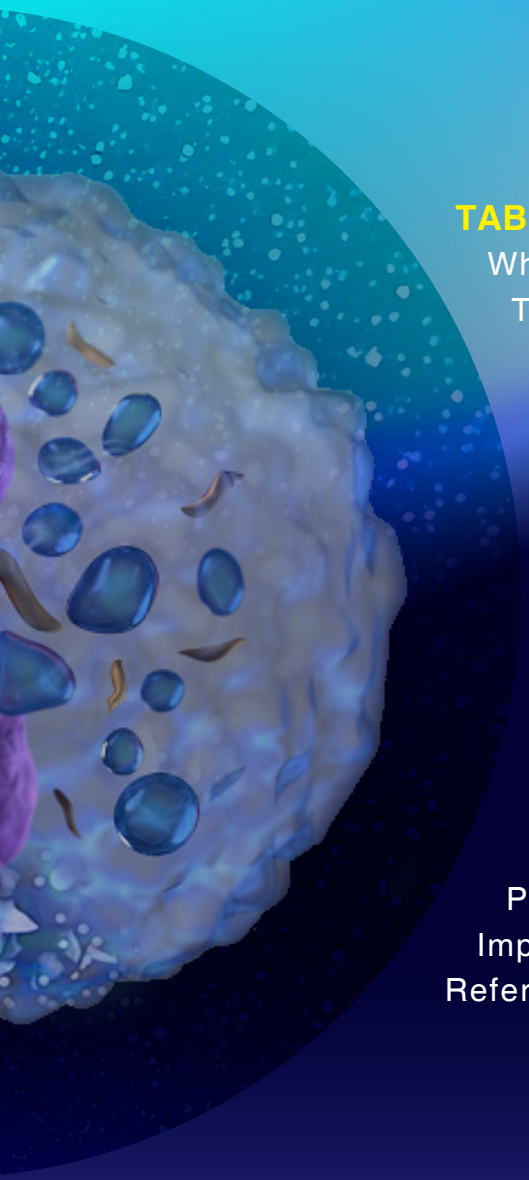
A New Frontier in GvHD Treatment

TASKIN BioRegeneration

Taskin *uses proven, innovative methods for better health outcome.*

TASKIN BioRegeneration





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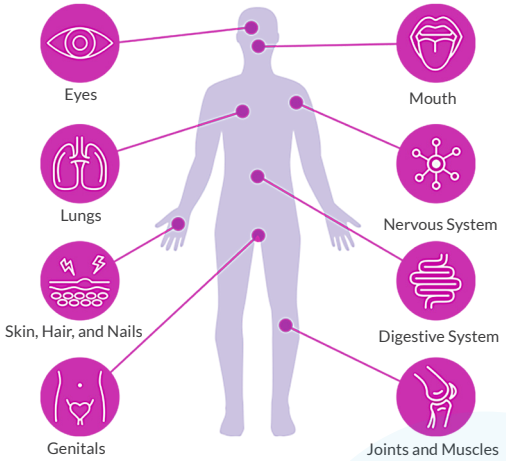
What Is Graft-Versus-Host Disease?

Graft-Versus-Host-Disease is a common complication following allogenic hematopoietic cell transplantation (HCT).

The condition is predominantly mediated by **donor T cells**, which recognize the recipient's tissues as foreign. This immune response triggers inflammatory cascade, resulting in tissue damage and clinical manifestations with high mortality rate.



Types of GvHD

Acute GvHD

Typically occurs within the first 100 days post-transplant, though it can develop later in some cases.

Commonly affected organs are:

Skin
Liver
Gastrointestinal tract

Chronic GvHD

Typically occurs after the first 100 days post-transplant, though it can overlap with acute GvHD. It is diagnosed based on Diagnostic and Definitive criteria.[12]

Staging of acute graft-versus-host disease (according to Harris et al. 2016)GVHD target organ staging

Stage	Skin (active erythema only)	Liver (bilirubin)	Upper GI	Lower GI (stool output/day)
0	No active (erythematous) GVHD rash	<2 mg/dL	No or intermittent nausea, vomiting, or anorexia	Adult: <500 mL/day or <3 episodes/day Child: <10 mL/kg/day or <4 episodes/day
1	Maculopapular rash <25% BSA	2–3 mg/dL	Persistent nausea, vomiting, or anorexia	Adult: 500–999 mL/day or 3–4 episodes/day Child: 10–19.9 mL/kg/day or 4–6 episodes/day
2	Maculopapular rash 25–50% BSA	3.1–6 mg/dL	–	Adult: 1000–1500 mL/day or 5–7 episodes/day Child: 20–30 mL/kg/day or 7–10 episodes/day
3	Maculopapular rash >50% BSA	6.1–15 mg/dL	–	Adult: >1500 mL/day or >7 episodes/day Child: >30 mL/kg/day or >10 episodes/day

Overall clinical grade (based upon most severe target organ involvement):
Grade 0: No stage 1–4 of any organ
Grade I: Stage 1–2 skin without liver, upper GI or lower GI involvement
Grade II: Stage 3 rash and/or stage 1 liver and/or stage 1 upper GI and/or stage 1 lower GI
Grade III: Stage 2–3 liver and/or stage 2–3 lower GI, with stage 0–3 skin and/or stage 0–1 upper GI
Grade IV: Stage 4 skin, liver or lower GI involvement, with stage 0–1 upper GI12].

CURRENT PROPHYLAXIS REGIMEN:[12]

Mycophenolate + CNI

- Mostly in reduced intensity conditioning (RIC)HCT

PTCy: (post-transplant cyclophosphamide)

- The classical Baltimore's PTCy prophylaxis includes CY on days +3 and +4 followed by CNI/MMF given from day +5. MOSTLY IN haploidentical cell transplant

MTX (methotrexate) + CNI

(calcineurin inhibitors: cyclosporine or tacrolimus)

- Mostly in myeloablative conditioning (MAC) HCT

Acute GvHD Treatment

For Grade II or higher GVHD, treatment typically includes systemic glucocorticoids, such as methylprednisolone. High-dose methylprednisolone (or an equivalent) is the mainstay of therapy, usually administered at 2 mg/kg/day for 7–14 days, followed by a gradual taper. Patients with mild upper gastrointestinal GVHD may start on lower doses combined with topical treatments, as higher steroid doses have been associated with increased infectious complications without superior long-term outcomes. Furthermore, the likelihood of response decreases as the GVHD grade increases. For patients with gastrointestinal involvement, non-absorbable oral steroids are commonly used as a local treatment.[12]

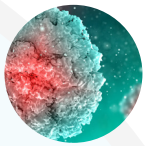
Steroid Refractory Graft Versus Host Diseasel (SR-GvHD)

Up to 60% of patients with acute GvHD develop steroid-refractory GvHD (SR-GvHD), a condition characterized by disease progression within 3–5 days or a lack of response within 7 days of high-dose glucocorticoid therapy, or by recurrence after an initial dose reduction (steroid dependence). There is no consensus regarding second-line therapies, aside from Ruxolitinib (a selective JAK1–2 inhibitor), which was recently approved by the FDA, despite its significant adverse effects and treatment-related toxicity. Therefore, alternative treatment options are necessary.

Limitations of Ruxolitinib in GvHD Traetment

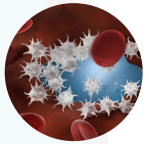
Ruxolitinib

Ruxolitinib is classified as a hazardous drug, indicating it may possess properties such as carcinogenicity, teratogenicity, reproductive toxicity, organ toxicity at low doses, or genotoxicity. Consequently, it has been associated with multiple side effects. Some of the most common adverse events limiting the use of Ruxolitinib include anemia, thrombocytopenia, bruising, dizziness, and headache.[uptodate]

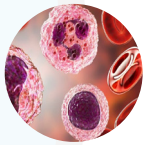


Increased Risk of Infections In Patients Treated With Ruxo, Especially Epstein-Barr Virus (EBV) And Cytomegalovirus (CMV) Reactivations.[13]

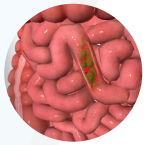
Anemia
(72% to 96%; grade 3: ≤34%; grade 4: ≤11%)



Thrombocytopenia
(27% to 70%; grade 3: 5% to 9%; grade 4: ≤4%)



Neutropenia
(3% to 19%; grade 3: 5%; grade 4: ≤2%)



Diarrhea
(15%)

Abdominal pain
(15%)[12]

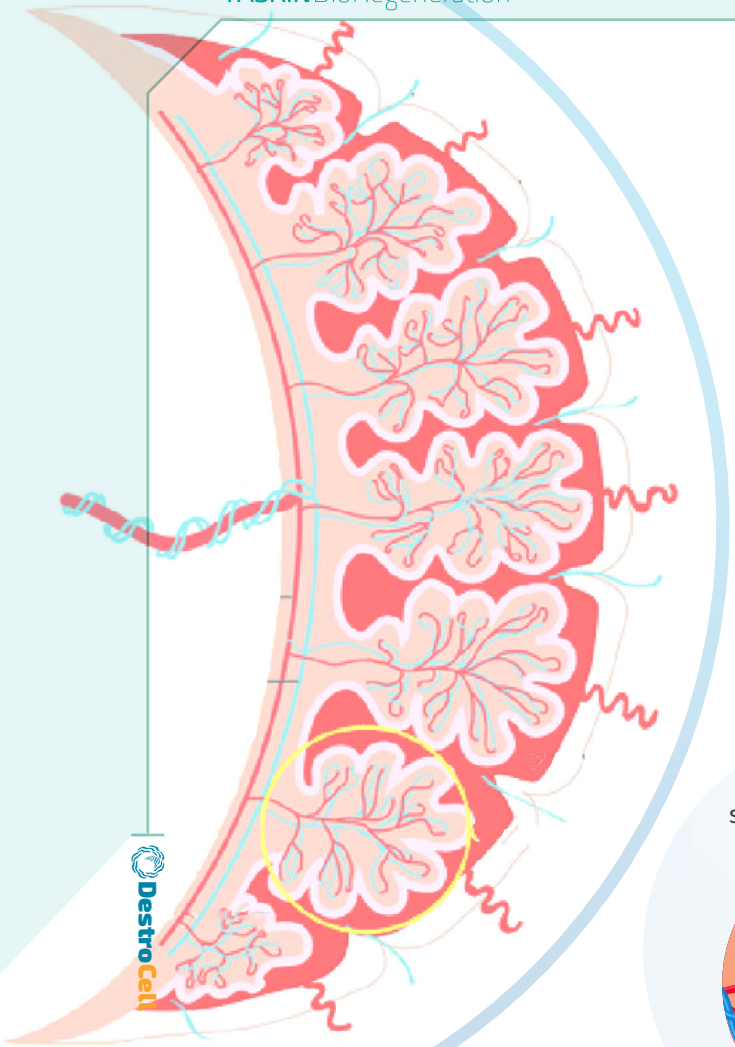
The Necessity Of a Novel Approch:

- **High Rate of GvHD DEVELOPMENT (up to 60%)**
- **High rate of SR-GvHD (up to 60%)**
- **Multiple Potential Side effects of corticosteroids and ruxolitinib**
- **High Mortality Rate** uptodate

Given the challenges highlighted the need for innovative therapeutic solutions has never been more urgent.

DestroCell

A New Frontier in GvHD Treatment



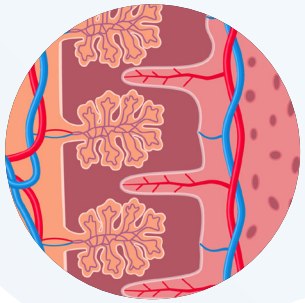
DestroCell

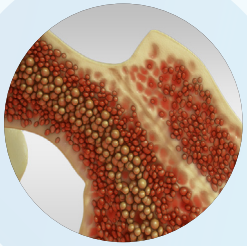
The Foundation of Innovation:[1,7,8]

About 20 years ago, bone marrow-derived mesenchymal stromal cells (BM-MSCs) were introduced as a treatment for steroid-refractory acute GvHD (SR-aGvHD). However, subsequent clinical trials and controlled studies have shown that while BM-MSCs are effective in some patients, they do not consistently work for all. This led us to explore alternative sources of more potent stromal cells.

The placenta plays a crucial role in protecting the semi-allogeneic fetus from the maternal immune system, serving as both a tolerogenic barrier and an immune modulator to prevent alloreactive immune responses. By isolating and expanding specialized stromal cells from the placenta, we successfully harnessed their natural ability to regulate the maternal immune system.

Building on this unique immunomodulatory mechanism, we developed DestroCell, a novel stromal cell therapy designed to treat acute GvHD and steroid-refractory GvHD more effectively.

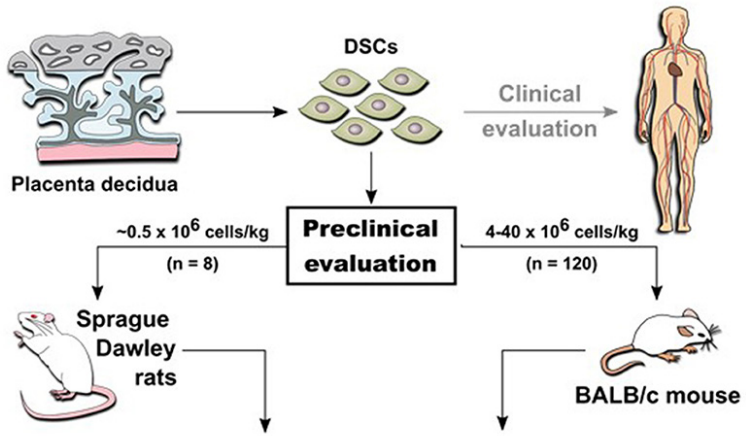




SAFETY PROFILE

Safety In Animal Models

Preclinical toxicity evaluation of clinical grade DSCs



Outcome:	Rat	Mouse
Number of deceased animals	none	none
Acute toxicity & side effects	none	none
Blood chemistry profile	normal	normal
Histological examination	normal	normal
Motility and behavior	normal	normal

Safety In Clinical Practice

Cell therapy using mesenchymal stromal cells (MSCs) appears to be safe, with meta-analyses involving over 1,000 patients reporting only a limited number of side effects.

Decidua stromal cells (DestroCell) have also demonstrated a strong safety profile, with over 500 infusions administered to patients in Sweden, Iran, and Canada. Unlike corticosteroids and other immunosuppressive treatments, which can significantly increase the risk of infections, DestroCell has shown only minimal side effects. Importantly, none of these side effects required additional medication for symptom relief or led to the discontinuation of cell infusion.

The most commonly observed side effects include:

- Transient fever
- Transient chills
- Transient headache and dyspnea (manageable with oxygen support)
- Transient vertigo
- Transient nausea

Mechanism Of Action

DestroCell effectively inhibits T-cell alloreactivity in mixed lymphocyte reactions (MLR). This inhibitory effect is independent of HLA compatibility between lymphocytes and DestroCells.

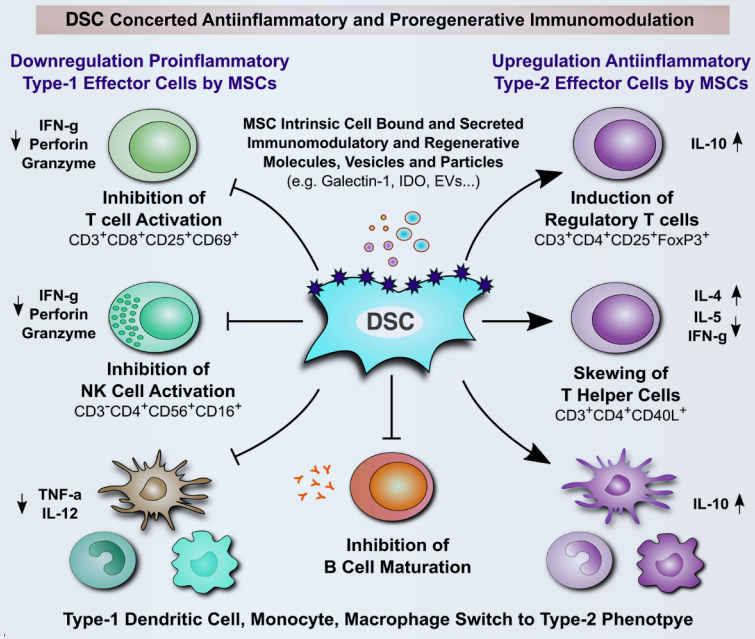
DestroCells exhibit high expression of programmed death-ligand 1 and 2 (PD-L1/PD-L2), which play a pivotal role in regulating lymphocyte proliferation and activation. Additionally, DestroCells enhance the frequency of $CD25^{+}$ regulatory T cells and promote the production of IL-10, contributing to their immunosuppressive function.

Beyond modulating T-cell responses, DestroCells also influence dendritic cells by reducing TNF-α and IL-12 production while promoting IL-10 secretion by lipopolysaccharide (LPS)-stimulated type 2 dendritic cells. Furthermore, DestroCells secrete several key immunoregulatory factors, including HLA-G5, prostaglandin E2 (PGE2), and indoleamine-2,3-dioxygenase (IDO). Notably, IDO profoundly suppresses T-cell activity by catalyzing the conversion of tryptophan to kynurenine, a well-established immunosuppressive metabolite.

In addition to secreting soluble immune modulators, DestroCells exert contact-dependent immunomodulatory effects. This includes the activation of the PD-1 pathway, as well as upregulation of vascular cell adhesion molecule-1 (VCAM-1) and intercellular adhesion molecule-1 (ICAM-1), which are involved in immune regulation. Moreover, DestroCells induce Fas-mediated T-cell apoptosis, further contributing to their immunoregulatory capacity.[10]

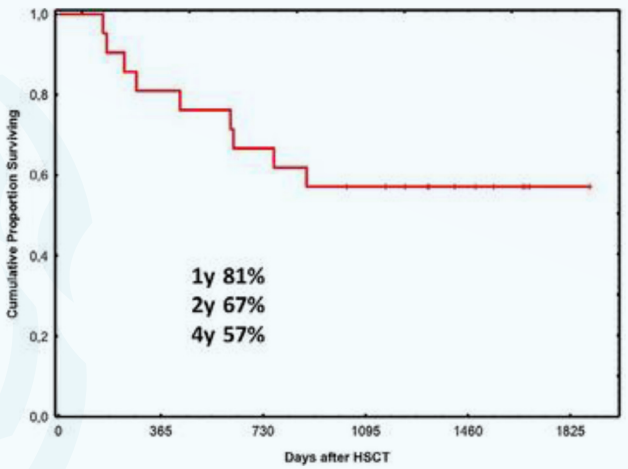
DSCs mainly suppress lymphocyte proliferation through both paracrine mechanisms and cell-to-cell contact. Importantly, DSCs from the placental fetal membrane induce substantially stronger inhibition of MLCs compared to BM-MSCs and other sources of stromal cells from the placenta , which may also relate to their strong potency to modulate immune responses in vivo. Apart from the secretion of soluble mediators, their direct contact-dependent effects include activation of the PD-1 pathway and the activation of VCAM-1 and ICAM-1. DSCs upregulate CD39 and adenosine production to suppress activated T cells and they also induce Fas-mediated

T cell apoptosis [11]

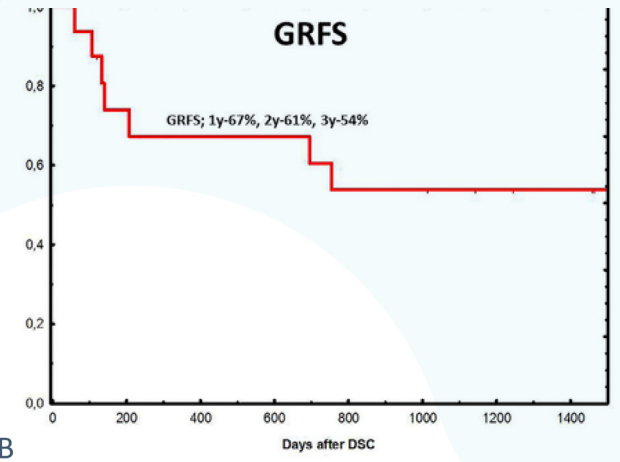


Proven Efficacy

Among growing number of studies exploring the potential of DSC therapy, four significant clinical trials conducted in Sweden, Canada and Iran provide compelling evidence. These studies included a total of 76 patients, including adults and children, treated for SR-GvHD grade 2-4 or hemorrhagic cystitis (HC).



A



B

FIGURE 1A: OVERALL SURVIVAL IN 21 PATIENTS TREATED WITH DSCS FOR SEVERE ACUTE GvHD, **FIGURE 1B**: PROBABILITY OF GRFS (GvHD -FREE RELAPSE-FREE SURVIVAL) IN ALL 21 PATIENTS FROM THE TIME OF DSCTREATMENT.[2]

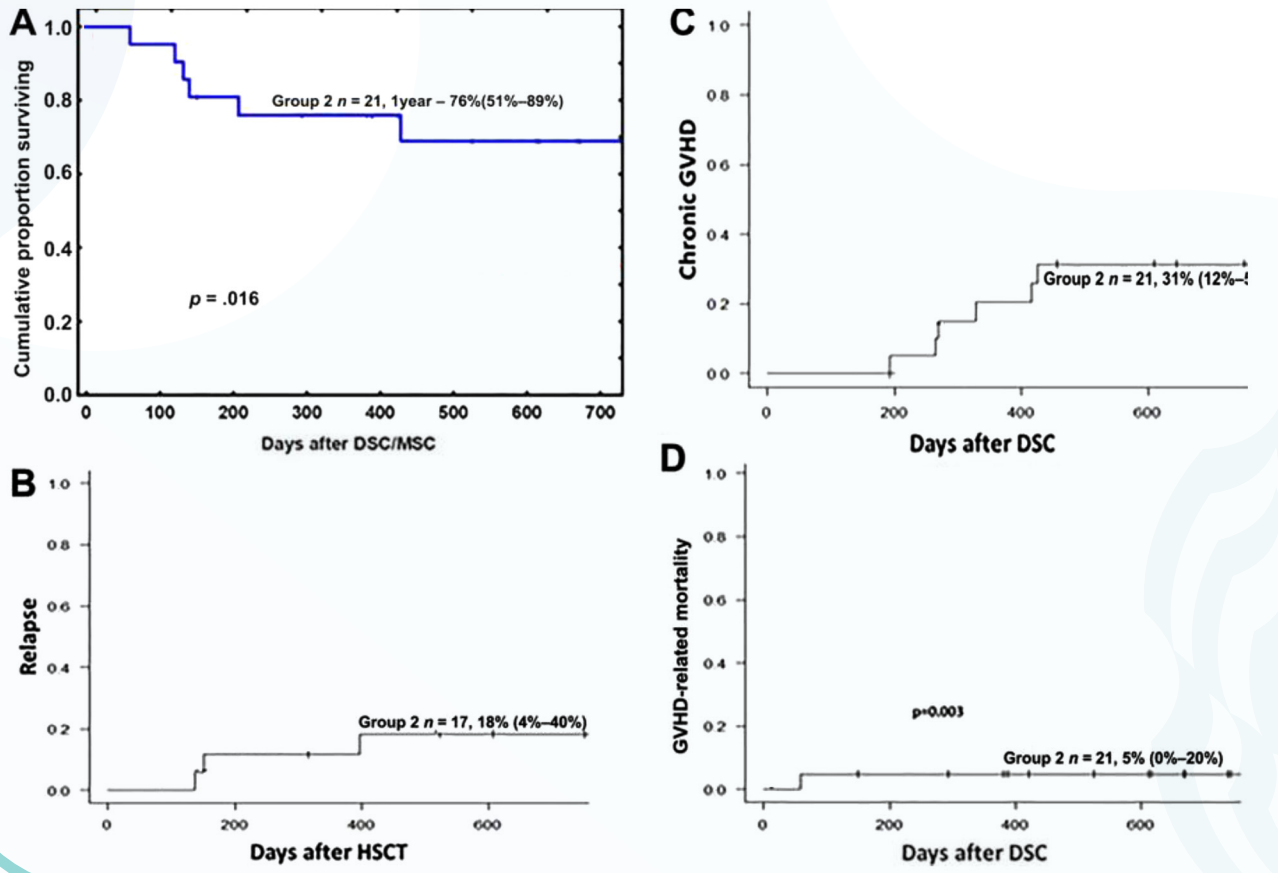


Figure2: (A): Kaplan-Meier estimate of the overall survival of patients with severe acute GvHD who were treated with DSCs. The patients were divided into two groups based on differences in the cell handling procedure (Table 1). Group 2 had a significantly higher chance of survival than group 1 (p5.016). There were no significant differences in the relapse incidence (B) or incidence of chronic GvHD (C) between the two groups. (D): The relative risk of having GvHD symptoms at the time of death was significantly higher for the patients in group 1 (p5.016). Abbreviations: DSC, decidua stromal cell; GvHD, graft-versus-host disease; HSCT, allogeneic hematopoietic stem cell transplantation; MSC, mesenchymal stromal cell. [3]Group 1 received a higher cell dose (p < .001), cells of lower passage number (p < .001), and fewer infusions (p 5 .002) than group 2).[3]

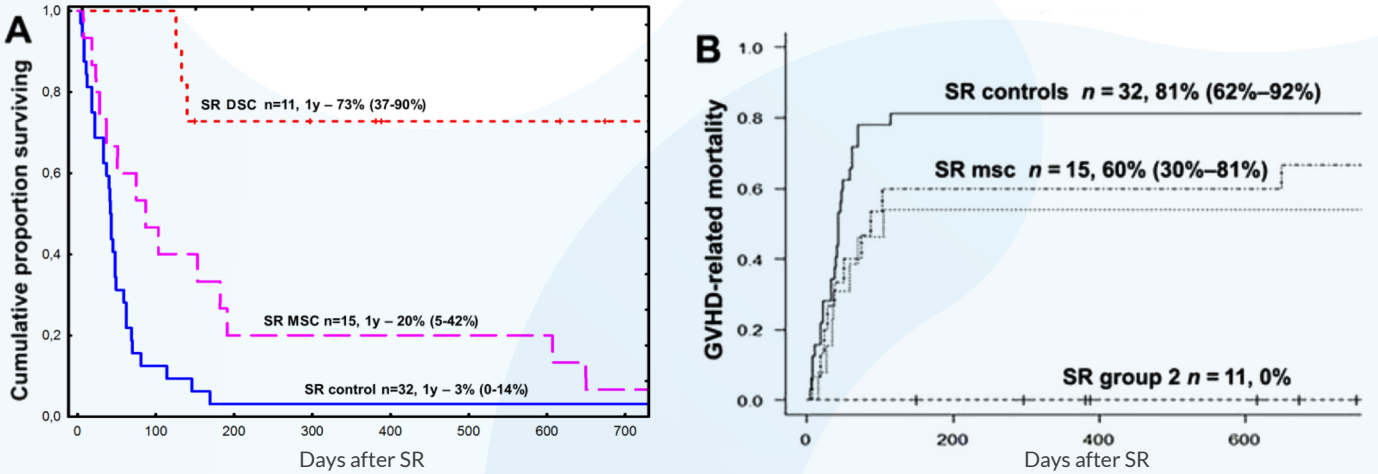


Figure3: (A): Kaplan-Meier estimate of the overall survival of patients with acute SR GvHD treated with decidua stromal cells and SR controls. SR group 2 had a significantly higher chance of survival than SR group 1 (p5.02), MSC-treated patients (p5.0015), and the SR controls (p<.001). (B): The relative risk of having GvHD symptoms at the time of death was significantly higher for SR group 1, MSC group, and the SR controls than for SR group 2, (p<.01; p<.01, and p<.001, respectively). Abbreviations: GvHD, graft versus- host disease; SR, steroid refractory; MSC, mesenchymal stromal cell [3].

Placenta-Derived Decidua Stromal Cells for Hemorrhagic Cystitis after Stem Cell Transplantation by Wictor Aronsson Kurttila highlights that 5 out of the 11 hemorrhagic cystitis (HC) patients experienced the disappearance of HC symptoms after DSC intervention. In addition, 3 other patients experienced the transient disappearance of symptoms. The most interesting group was that of the 3 patients who received DSCs within 3 days of the start of HC. These patients were all free from macroscopic hematuria within 5 days and they were pain free within 9 days. These findings were highlighted in.[30]

Mesenchymal Stromal Cells in Pediatric Hematopoietic Cell Transplantation a Review and a Pilot Study in Children Treated with Decidua Stromal Cells for Acute Graft-versus-Host Disease by Olle Ringdén highlights that a t 6 months, among 6 children with SR-GvHD with a median age of 7 years, a complete response was observed in 4 patient and partial response in two patients.[4]

DesrtoCell: The Difference Matters

Differences between DestroCell Vs BM-MSCs

	DSC	MSC
Tissue origin	Placenta & FM	Bone marrow
Differentiation to fat and cartilage	+/-	+++
Size, volume	2400 f l	4600 f l
Express PD-L1, PD-L2	++	+/-
Needs IFN-γ licensing for activation	-	++
Inhibition of lymphocyte proliferation (MLC)	++++	++
Induction of T reg frequency	++	+
Clinical Efficacy	++++	+/-

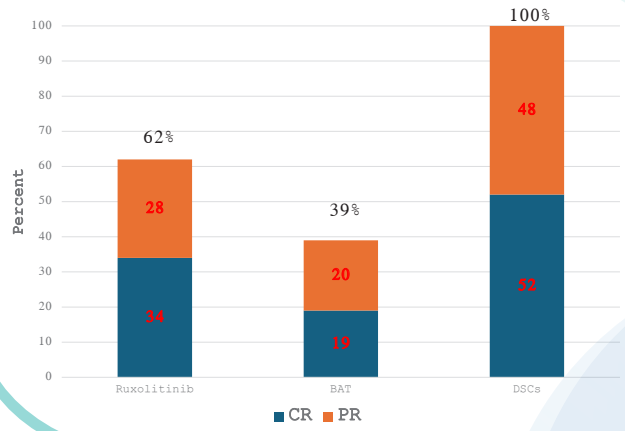
Clinical Safety and efficacy of DSCs Vs Ruxolitinib in SR-GvHD

Adverse reaction	Ruxolitinib	BAT	DSCs
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 discontinuation (TD)	72% [1]	85% [1]	0% [2]
TD due to Lack of efficacy	21%[1]	44%[1]	0% [2]
Any Adverse 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; 382:1800-1810
2 Ringden, O., et al. STEM CELLS TRANSLATIONALMEDICINE 2018;7:325–332

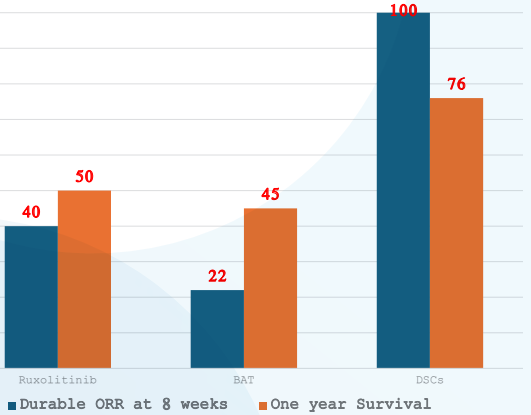
BAT: best available treatment

Overall Response rate (ORR) at 4 weeks (CR+PR)

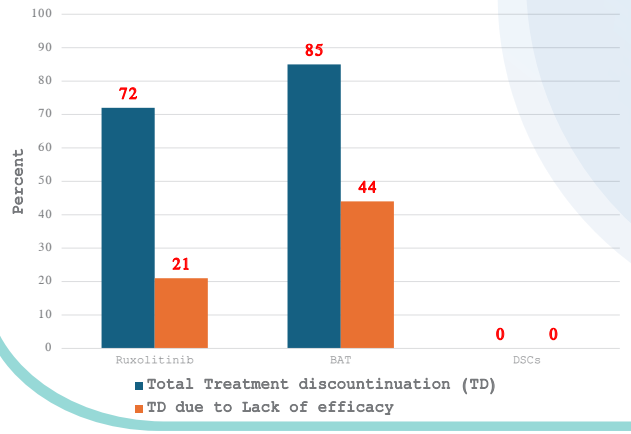


CR: complete remission, PR: partial remission

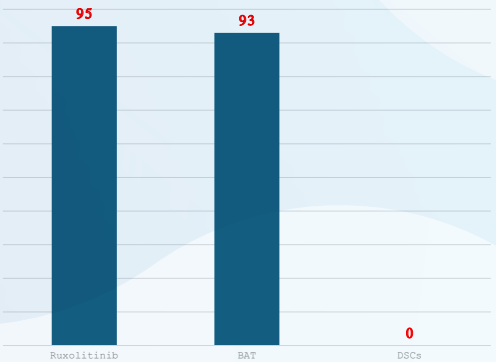
Results



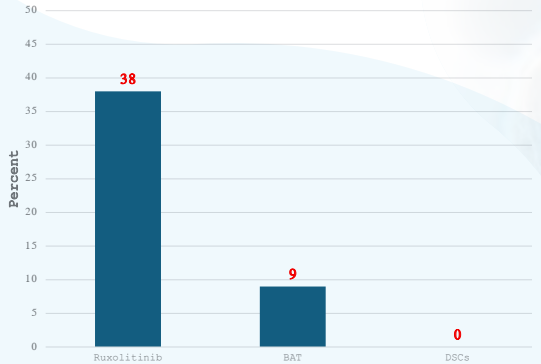
Treatment discontinuation (TD)



Any Advers Events (AEs)

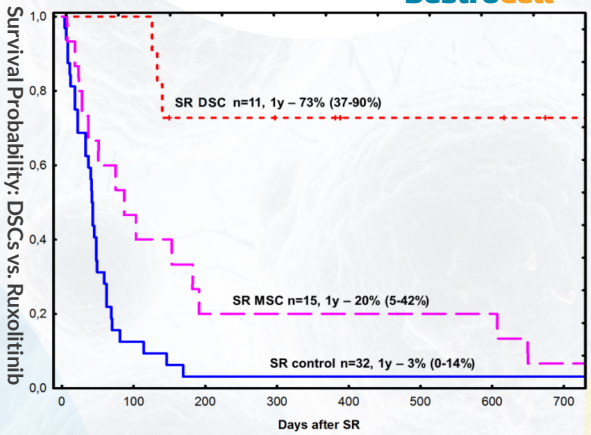


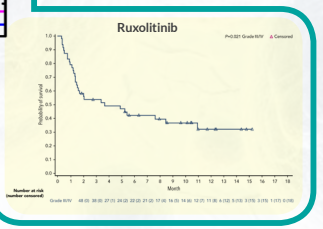
Dose Modification due to AEs at day 28



Cumulative Proportion Surviving

DestroCell





DestroCell

What Is DestroCell?

SOURCE:

IT DRIVES FROM DECIDUAL MESENCHYMAL STROMAL CELL (DSC)

How Is It Obtained

DestroCell is obtained from the stromal cells of decidual part of term placentas donated by healthy mothers, following elective cesarean section, with informed constant. Ethical approval was obtained from the Institutional Ethical Review Board. The donors were seronegative for HIV, hepatitis B and C, and syphilis.

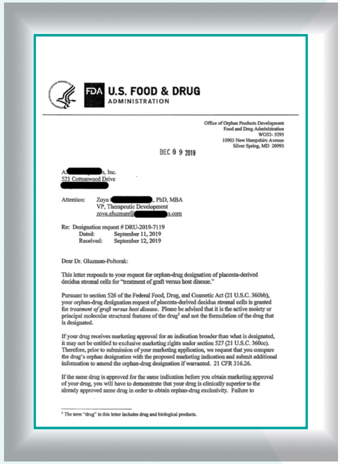
Product Achievement

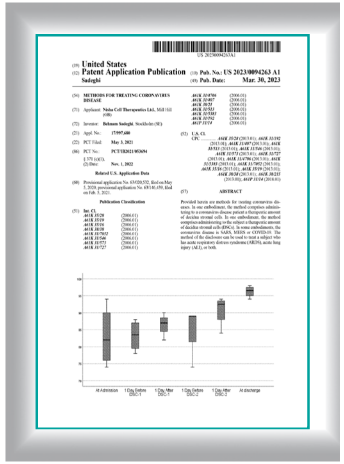
- DestroCell IS THE FIRST IRANIAN ALLOGENIC LIVE CELL
- APPROVED IND BY US FDA
- ODD(Orphan drug designation) BY FDA AND EMMA

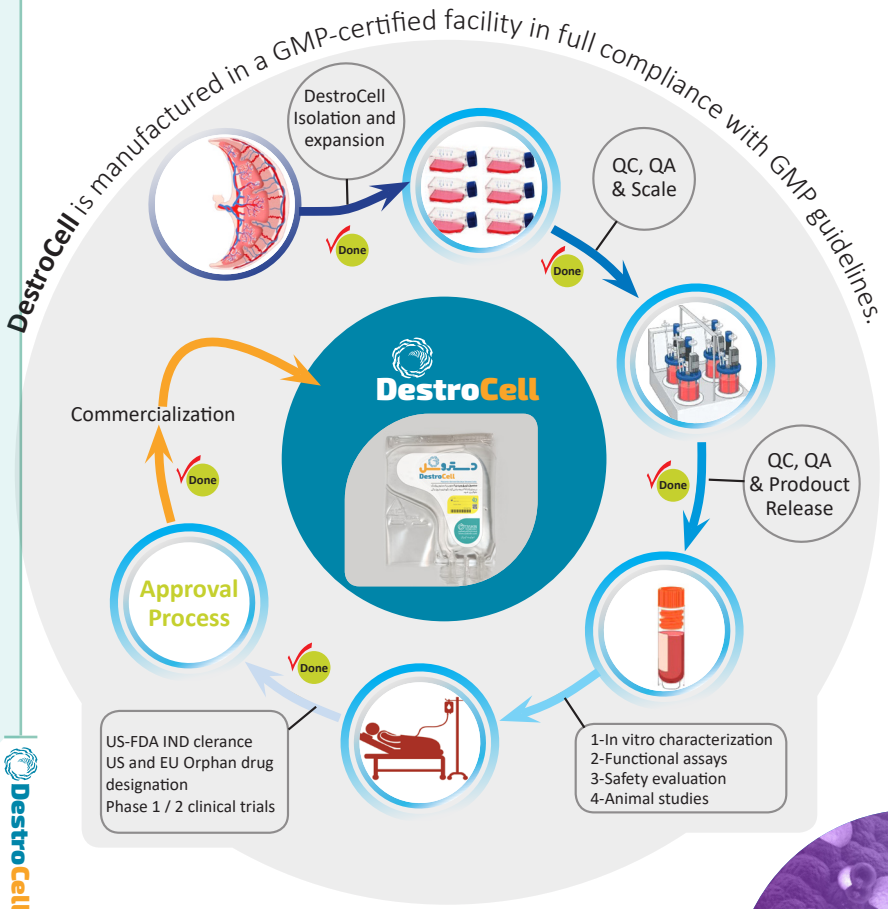
Approval Status

IRAN FDA

Certifications







Composition

Each bag contains 75 ±5million live cells suspended in 40 ±5ml of a solution composed of 5 %human albumin and 0.9% sodium chloride

Indications

Acute-GvHD and SR-GvHD (acute and steroid refractory graft-versus-host-disease)

Contraindications

- Patient receiving or having recently received infliximab
- Patients with sinusoidal obstruction syndrome
- Patients with active pulmonary embolism
- History of allergic reactions to cell therapy products
- Severe systemic fungal infections
- Pregnant or lactating women, as safety has not been studied in these populations

Recommended Dose

Generally, the recommended dose is $1x10^6$ cells/kg per week. Depending on disease severity, patients may receive between 4 and 8 therapeutic doses. For pediatric patients, the dosage is half of the adults. The infusion time is between 20 and 30 min.

Administration Instructions

The provided cell suspension is ready-to-use and requires no further preparation. Administer via intravenous infusion, preferably through a central line.

Storage Conditions

Store at a temperature range of 15-37°c. The cells remain viable at room temperature (below 37°c), but freezing is strictly prohibited.

The Treatment Process:

FROM START TO FINISH

Step1:
Preparation 1-3 days

Step2:
Infusion 20-30min

Step3:
Post-Infusion Monitoring 1-3 Days and Beyond

our healthcare team is always available to address your questions and concerns you might have and ensure the best outcomes for your patients.
do not hesitate to reach us out for support.

STEP1: **Preparation**

Confirm that the patient is free from active infection.
Check blood tests: CBS, LFT, FBS, ESR, CRP, D-DIMER, PT, PTT, INR, Na, K, Ca, albumin, Uric acid, BUN, Cr and U/A …
Verify that the patient has no history of seizures or major cardiopulmonary abnormalities.

STEP2: **Infusion**

It is recommended to provide 100mg IV hydrocortisone or Chlorpheniramine 10 mg IV (or 20 mg IM) 30min prior to infusion in order to minimize the risk of allergic reactions during infusion.
Flush the injection line and catheter with 5000 units of heparin in 5ml immediately before and after administering DestroCell to improve efficacy and minimizing coagulation risk.
For pediatric patients, use half the dose of heparin.
DestroCell will be administered via IV preferably central line which takes approximately 20-30 minutes.

STEP3: **Post-Infusion Monitoring**

Closely monitoring the patients for 3 days is essential.
Vital Signs Monitoring: record at baseline, then every 30 minutes for the first 2 hours, hourly for the next 2 hours, and then at the 6-hour mark.
Check for any possible side-effects including, allergic reaction, dyspnea, tachycardia or bradycardia, vertigo, rigors and fever.
It is vital to inform us if anything mentioned above happens.
Routine hematological monitoring post infusion is recommended to detect and manage these complication.

IMPORTANT SAFETY INFORMATION

Key Information About Destrocell

DestroCell IS THE FIRST IRANIAN ALLOGENIC LIVE CELL SUSPENTION CONTAINING STROMAL CELLS DERIVED FROM DECIDUAL PART OF PLACENTA.

DestroCell is derived from the decidual part of term placentas donated by healthy mothers, following elective cesarean section, with informed consent. Ethical approval was obtained from the Institutional Ethical Review Board. The donors were seronegative for HIV, hepatitis B and C, and syphilis.

Before Administering DesreoCell, Assess The Following

- Current or previous neurological conditions (e.g., seizures, stroke or changes in cognitive functions such as memory loss)
- Major cardiopulmonary abnormality
- Active or recent infections
- All your patient's medications

Indications

- Acute-GvHD and SR-GvHD (acute and steroid refractory graft-versus-host-disease)

Contraindications

Patient receiving or having recently received infliximab, atients with active pulmonary embolism, systemic fungal infection, pregnant or lactating women, as safety has not been studied in these populations

How Will Be Destrocell Administered?

Confirm that the patient is free from active infections .Verify that the patient has no history of seizures or major cardiopulmonary abnormalities. Check blood tests: CBS, LFT, FBS, ESR, CRP, D-DIMER, PT, PTT, INR, Na, K, Ca, albumin, Uric acid, BUN, Cr and U/A. It is recommended to provide 100mg IV hydrocortisone or 150mg IV chlorpheniramine 30 min prior to infusion in order to minimize the risk of allergic reactions during infusion. Verify patient information on the injection bag and inspect for leaks or cellular clots. If significant clumps are present, retrain from using the product. Ensure the suspension is clear, free of large clots, and not frozen or discolored before use, Use the filtered infusion set for administration. Flush the injection line and catheter with 5000 units of heparin in 5ml immediately before and after administering DestroCell to improve efficacy and minimizing coagulation risk. For pediatric patients, use half the dose of heparin. DestroCell will be administered via IV which takes approximately 20-30 min, gently agitating the bag during infusion to ensure homogeneity. Closely monitoring the patients for 3 days and beyond is essential. Vital signs monitoring: record at baseline, then every 30 minutes for the first 2 hours, hourly for the next 2 hours, and then at the 6-hour mark.

Check for any possible side-effects including, allergic reaction, dyspnea, tachycardia or bradycardia, vertigo, rigors, fever and calf swelling.

it is vital to inform us if anything mentioned above happens.

Adverse Reactions

Like any biological or chemical treatment, DestroCell may cause side effects in addition to its therapeutic benefits. Based on clinical studies, no serious adverse reactions have been reported. Among 100 patient treated with DestroCell, only a few experience mild symptoms such as dizziness, headache, and tachycardia. These symptoms resolved spontaneously without medical intervention. However, as with other biological therapies, the following potential side effects should be monitored by the medical team.

Post-Treatment Care Guideline

Patients must avoid driving, operating heavy machinery, or performing any activities that require mental alertness for at least 8 weeks after receiving DestroCell. Be mindful of potential side effects such as coordination issues, drowsiness, confusion, dizziness, or other neurological symptoms. Patients cannot donate blood, organs or cells for transplantation.

The Most Possible And Common Side Effects Of DestroCell

Fever (38°c or higher), inflammatory reactions typically occur within the first24 hours after administration. Rigors, vertigo, headache, arthralgia, altered mental status, cough, dyspnea, tachycardia, hypercoagulability state and thrombosis. Routine hematological monitoring post-infusion is recommended to assess patient's response and the need for additional DestroCell dose. It is essential to monitor patients closely and act promptly if they exhibit fevers, rigors, or any other signs and symptoms.

The Most Possible And Common Side Effects Of DestroCell

Regular surveillance is required to identify and address any relapsing malignancies. This list does not encompass all possible adverse events. Healthcare professionals should monitor patients closely, provide counselling and report any unexpected outcomes to ensure optimal care and patient safety.

Administration Instructions

The provided cell suspension is ready-to-use and requires no further preparation. Administer via intravenous infusion, preferably through the central line.

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The provided cell suspension is ready-to-use and requires no further preparation. Administer via intravenous infusion, preferably through a central line.

Storage Conditions

Store at a temperature range of 15-37 ˚c the cells remain viable at room temperature (below 37˚c), but freezing is strictly prohibited.

Incompatibility

Comprehensive studies on drug compatibility have not been conducted. However, based on clinical findings, DestroCell is contraindicated for use with infliximab. Current use with cytotoxic drugs (e.g. ATG) is not recommended, as it may reduce the effectiveness of DestroCell.

Expiration

The prepared infusion solution is viable for 12 hours after if stored at room temperature (15-37˚c).

References

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