

Demand

Post-transplant patients become vulnerable to different kinds of infections like fungal, bacterial, and viral. Viral infections in immunocompromised patients had led to mortality and morbidity rates witnessed by bone marrow transplant (BMT) professionals around the globe.

Innovative Approach

Researchers who had been working towards a solution had invented an anti-virus T cell (AVTC) product that can protect the patients from viral infections. The innovative product depends on creating virus-specific T cells that identify and eliminate the infected cells.

Canada ¹ (n=844)	KSA ² (n=131)	USA ³ (n=124)
RVI* (28%)	CMV (29%)	CMV(20%)
		ADV (53%)
		EBV (38%)
		BKV (54%)
	mortality: 10%	Mortality: 10%
*Parainfluenza, RSV, influenza, Adenovirus, human metapneumovirus, coronavirus, rhinovirus		
2: Journal of Applied Hematology Vol. 7 • Issue 2 • April-June 2016		
1: Adam Gassas, 2015 Biol Blood Marrow Transplant 21 (2015) 1802e1807		
3: Ozdemir et al, Tandem Meeting 2012		

AVTC Production

- Identify a good match of your patient
- Isolate MNC from the donor
- Pulse the MNC fraction with virus-specific peptides
- Cultivate the cells for 9-12 days to reach the target cell number
- Harvest the cells and cryopreserve them

The list of equipment will depend on your manufacturing model. Example equipment:

- Biosafety cabinet
- FACS
- Controlled rate freezer
- Automated cell counter
- Incubator
- Centrifuge
- Freezers

Testing

- Safety (contamination free, low off-target activity)
- Purity (dominated by T cells)
- Efficacy (active against infected cells)
- Identity (end product and starting product are identical)
- Quantity (enough cells for the therapeutic dose)

The list of documents will vary from one production model to another and from one institute to another, but some required documents are:

- Standard Operating Procedure
- Production Record
- Certificate of Analysis
- In-process Testing
- Material Specifications
- Training record
- Product label

Release and Infusion

When all release criteria are met, prepare the cells (thaw/wash/dilute, or thaw and infuse) for your patient.