

FORM 2

AIET/PTDF

**PRE TREATMENT DATA FORM
AUTOLOGOUS IMMUNE ENHANCEMENT THERAPY (AIET) for CANCERS**

This form must be completed by the attending Physician in BLOCK LETTERS

PATIENT'S PARTICULARS		
Name as per NRIC or Passport :	Age:	Male <input type="checkbox"/> Female <input type="checkbox"/>
Correspondence address :		
Patient's Signature:	Citizenship(Country) :	
	Tel: (Fax) :	
NRIC No / Passport No.:	(H/P)	Email

H/o smoking <i>Yes / No</i>	Diagnosis:
H/o intake of Alcohol <i>Yes / No</i>	
Family history of malignancy <i>Yes / No</i>	

Latest Results of the following Investigations:

Date	Test	Result
	Hepatitis B	
	Hepatitis C	
	Total WBC	
	Differential Count	
	Platelets	
	Volumetric Analysis of tumour(s)	
	Tumor Burden by CT	
	Status of Metastasis (if applicable)	
	Tumor Markers	
	Quantification Data(if done)	

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Investigations done to confirm the above diagnosis

Date	Investigations	Results

Treatment undergone - Full details with drugs/regimes etc/alternate therapy

Date	Treatment Procedures	Results
	Surgery	
	Radiotherapy	
	Chemotherapy	

Treatment in Progress (Full details of drugs /regimes etc)

Date	Treatment	Results
	Surgery	
	Radiotherapy	
	Chemotherapy	

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Planned Future treatments - surgery, chemotherapy and/or radiotherapy

Date	Treatment	Remarks
	Surgery	
	Radiotherapy	
	Chemotherapy	

Expected Prognosis with current Treatment

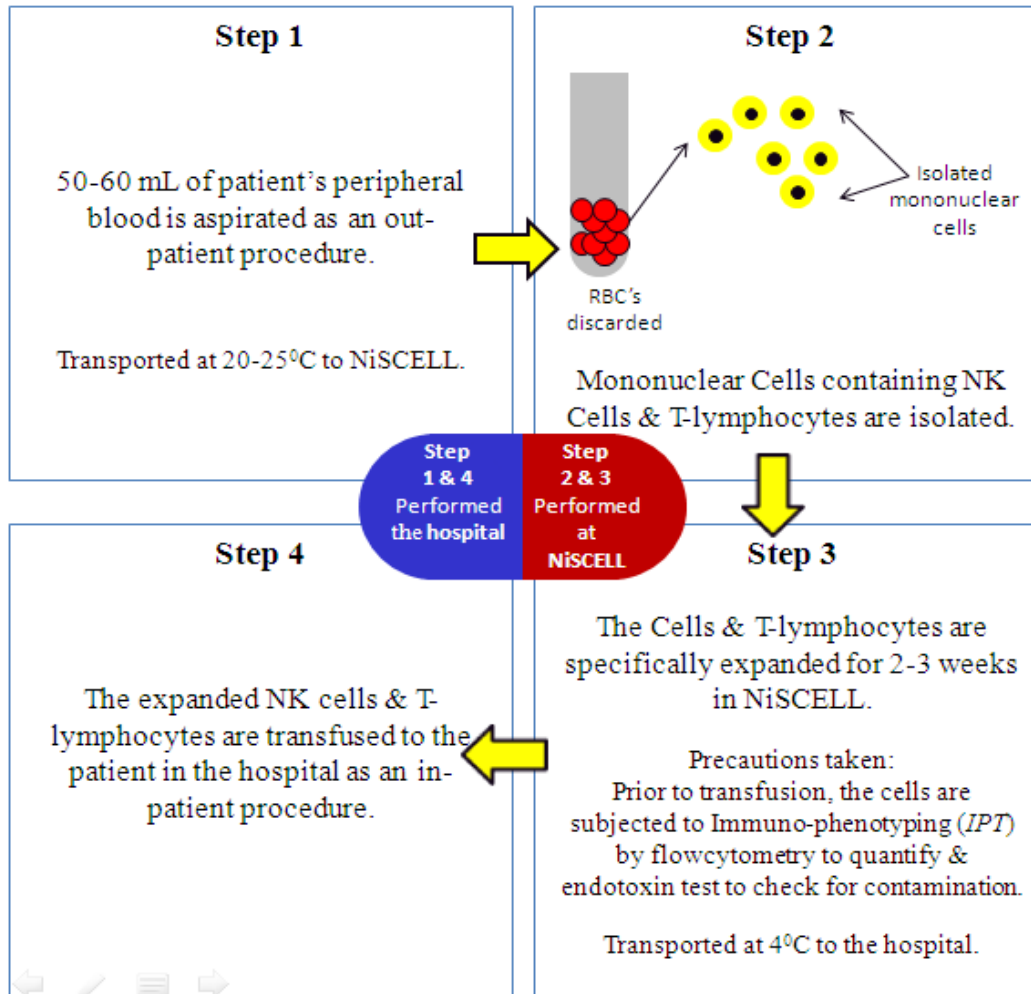
6months	1year	5 years

ATTENDING PHYSICIAN	
Physician's Name :	Tel(o): fax: (H/P): Email:
NRIC. Number :	Name & Address of hospital :
Physician's Signature:	
Date:	

How did you know about NiSCCELL?

Doctor	
Friend	
Family Member/Relative	
TV / Newspaper/Journal/ Internet	
Others-please name	

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FREQUENTLY ASKED QUESTIONS

1. What is immunotherapy?

This is a process of enhancement of the innate immunity present in all individuals. In Immunotherapy Lymphocytes and NK cells are taken from the patient's own blood and then in the laboratory (in vitro) lymphocytes and NK cells are activated as well as expanded, and then transfused back into their body through IV procedure.

2. How does it work and can it be used for all cancers?

The Lymphocytes are the first line of defense in our body against Cancer cells; especially the NK cells. They are very efficient because they cause direct cell lysis (direct damage to cancer cells) and do not need activation by antibodies.

Yes it is applicable for all cancers in general.

3. Does the immunotherapy necessitate admission of the patients to a hospital?

The patient need not be admitted for collection of blood as it can be done as an outpatient procedure. The patient has to be admitted for administering the cultured cells for about a day or two.

4. What are all problems that are anticipated during the administration of the cells?

In general there are no major adverse effects. This is so because the patients are given back the cells that were originally collected from them. Therefore the infusion is well tolerated. But during the process of destruction of the cancer cells by the cultured cells that are transfused, the patient may experience fever/fatigue on the day of administration. The risk of this is however is small. It occurred in less than 1% of patients in a study population that included more than 1400 patients.

5. What precautions does NiSCCELL take during the culture?

a) The culture technique is sterile so as to ensure that no bacterial contamination takes place. This is also objectively tested by using Endotoxin test. If it is negative it implies that there is no bacterial contamination and only then will the cultured cells be administered to the patients.

b) The collected cells will be subjected to IPT (Immunophenotyping) this is especially important for Blood cancers. After expansion, the cultured cells will once again be subjected to IPT and only on fully satisfying ourselves that the desired cells are present, they would be administered to the patients.

6. What are the Dosage requirements and timing of administration?

The dose is determined on a case to case basis. If the cancer is solid and has been removed completely by surgery 2 transfusions may be sufficient while 4 –6 Transfusions are required if the patients is receiving chemotherapy after surgery. 4 –6 Transfusions are required for blood malignancies. The timing for blood malignancies is when the patient is in remission. The timing for solid cancer is just before the patient is to receive chemotherapy or after 1 week of the patient receiving chemotherapy. This is to ensure that a good amount of peripheral blood Lymphocytes and NK cells are available for the treatment process.

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7. Is there any time frame for administering Immunotherapy (NK Cells and T Cells) during the course of Chemotherapy?

Peripheral Blood can be harvested from the patient during chemotherapy, but the activated immune cells (*NK Cells and T Cells*) when transfused needs a chemo-free window period of three day before and 3 day after transfusion. (i.e on the day when we give AIET transfusion before 3 days chemo should have been stopped and then should be started three days after the transfusion)

8. Is there any possibilities if the patient wants to infuse Activated Immune Cells before 14 days culturing period?

Yes, but the number of cells will be lesser compared to the number of cells after 14 days culturing.