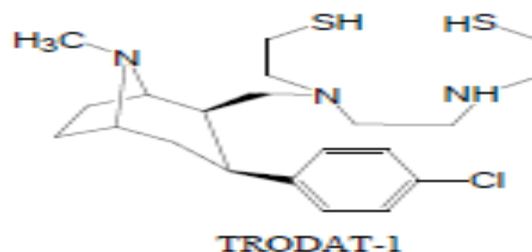




MEALIS
MEA Life Science

TroDAT-1

The First Commercialized Tc-99m labeled Radiopharmaceutical for Imaging Dopamine Transporters



Introduction:

Parkinson's disease (PD) is a common progressive neurological disorder that results from degeneration of nerve cells in a region of the brain that controls movement. The recent development of tracers for positron emission tomography (PET) and single photon emission computed tomography (SPECT), in conjunction with dedicated imaging devices, provides valuable tools for *in vivo* diagnosis and treatment of PD and related neurodegenerative diseases.

Tc-99m-TRODAT-1, which binds to the dopamine transporter (DAT) located on the presynaptic nerve endings in striatum, has been reported by Dr. Hank F. Kung as a SPECT imaging compound for diagnosing and monitoring the treatment of Parkinson's disease patients.

TRODAT-1 kit, all-in-one kit formulation for the preparation of Tc-99m-TRODAT-1, is the second radiopharmaceutical being commercialized as imaging dopamine transporter in the world. With the extensive availability of Tc99m and ability to stock the cold kits, it is generally accepted that Tc-99m-TRODAT-1 will be much more competitive than DATscan, an I-123 labeled DAT imaging agent being marketed across Europe.

FORMULATION

- TRODAT-1 Kit is presented as an all-in-one lyophilized kit. The formulation is patented in Taiwan, ROC.

- Each 10 ml-vial contains a pre-dispensed mixture of 126 μ g TRODAT-1·3HCl.
- No bacteriostatic preservative is present.

- After reconstitution with sterile Sodium Pertechnetate Tc-99m injection, the Tc-99m-TRODAT-1 formed is suitable for Intravenous injection.

Clinical Utility of Tc-TroDAT-1

Tc-99m-TRODAT-1 binds to the dopamine transporters (DAT) located on the presynaptic nerve endings in striatum. When neuronal degeneration is present, the numbers of DAT are significantly reduced. By detecting the binding of Tc-99m-TRODAT-1 to the dopamine Transporters, physician will have a clear visualization of dopamine transporter integrity and consequently an accurate diagnosis of disease..

Indications and usage

Imaging of dopamine transporters located in the dopaminergic presynaptic neuron terminals in the striatum.

Possible undesirable effects of administration of Tc-99m-TRODAT-1

Dizziness, back pain, hypertension and parenthesis have been reported occasionally.

INER TRODAT-1 Kit is a medicinal product for diagnostic use only.

Manufacture:

Radiopharmaceutical Production Center, Institute of Nuclear Energy Research. Atomic Energy Council.

TRODAT - 1

Preparation of Tc-99m-TRODAT-1

Place one lyophilized TRODAT-1 kit vial in a suitable lead-shielding container.
Using a 5 mL syringe, inject into the shielded vial 5 mL of Sodium Pertechnetate Tc-99m solution.
Withdraw 5 mL of gas from the space above the solution to maintain atmospheric pressure within the vial.
Autoclave the shielded vial at 121°C for 30 min.
After cooling to room temperature, the Tc-99m-TRODAT-1 formed is suitable for intravenous injection.



Dosage and Administration

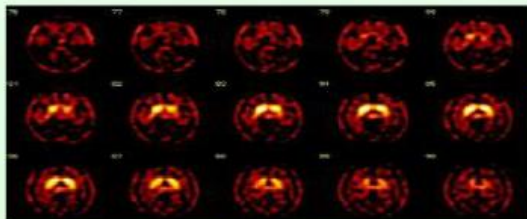
The recommended dose range for I.V. administration of Tc-99m-TRODAT-1 in a single dose to be employed in the average patient (70 kg) dose is 814-1036 MBq (22-28 mCi).
SPECT imaging should be performed after 3-4 hours post-administration.



Preparation of Tc-99m-TRODAT-1



Administration of Tc-99m-TRODAT-1 solution intravenously



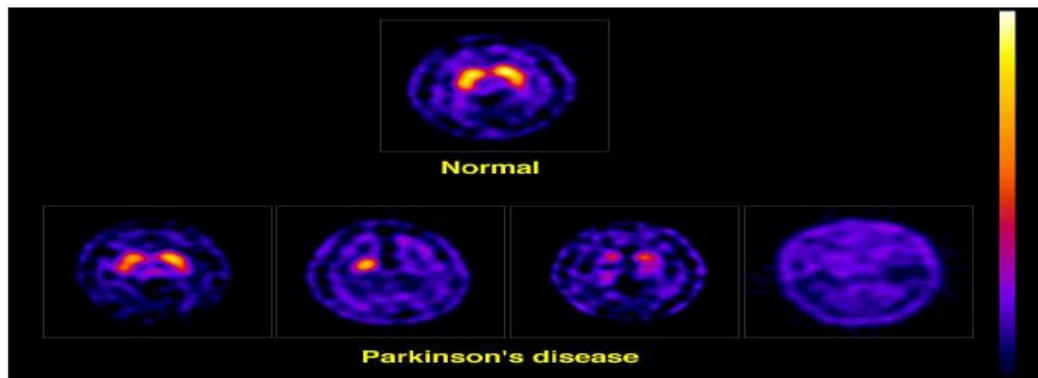
Acquisition of images



Imaging a patient on a SPECT

Diagnosis

The differentiation between a normal and abnormal distribution is primarily based on shape which reflects differences of uptake intensity.



References:

1. PET AND SPECT OF DOPAMINE TRANSPORTER • Varrone and Halldin
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