18F-Fibroblast Activation Protein Inhibitor (18F-FAPI-74) in Tuberculosis Patients

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 18 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion criteria: Patients may be enrolled into this protocol only if all the following inclusion criteria are met:

- Greater than or equal to 18 years of age
- Culture confirmation of M. tuberculosis, or sputum positive by molecular testing (GeneXpert).
- Imaging evidence of suspected M. tuberculosis disease involving lung, and possible additional other sites of involvement. Modalities can include any imaging modality such as chest x-ray, CT, ultrasound, MRI, 18F-2-fluoro-2-deoxy-D-glucose fluorodeoxyglucose ([18F]FDG) PET/CT, bone scan.
- TB treatment initiation within 6-weeks by the time of the study PET/CT scan OR within 6-weeks after receiving 6-months of TB treatments. Using this approach, we will be able to assess fibrosis in TB patients at treatment initiation as well as having received TB treatments. The same patient may be re-consented for a scan at the later time-point.
- Subject is willing to give written informed consent.
- Subject is willing and able to comply with the protocol for the duration of the study including undergoing scheduled visits and study procedures.
- Screening clinical laboratory values must be within normal limits or judged not clinically significant by the investigator.
- Women of child-bearing potential (WOCBP) must have a negative serum or urine pregnancy test within 24 hours prior to the radiotracer administration.
- Patients or their legal representatives must have the ability to read, understand and provide written informed consent for the initiation of any study related procedures.

Exclusion criteria: Patients will be excluded from enrollment if any of the following apply:

- Inadequate venous access (two antecubital or equivalent venous access sites are required for study drug injection and pharmacokinetics (PK) blood sampling, respectively)
- Lactating females
- Administered a radioisotope within 5 physical half-lives as part of a research study prior to study enrollment.
- Determined to have prior (external) radiation exposure from research studies which will exceed Radioactive Drug Research Committee (RDRC) annual radiation exposure limit of 5 rems.
- Any medical condition that in the judgment of the investigator would make the patient inappropriate for entry into this study.

Conditions & Interventions

Interventions:
COMBINATION_PRODUCT: 18F-FAPI-74
Conditions:
Tuberculosis, Pulmonary

More Information

Description:
The investigators will assess the hypothesis is that 18F-Fibroblast Activation Protein Inhibitor (18F-FAPI-74) Positron emission tomography (PET) could be used as a noninvasive biomarker to assess post-tuberculosis (post-TB) lung disease and fibrosis in TB patients. Microbiologically confirmed patients with active tuberculosis will be invited to participate in the study. A whole-body PET scan will be performed after 18F-FAPI-74 intravenous injection and correlation will be made with sites of TB lesions noted on CT. It is anticipated that 18F-FAPI-74 PET will be able to detect fibrosis (with high sensitivity) in the TB lesions.

Contact(s): Kerrigan Perkins - kerrigan.perkins@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase:
IRB Number:
System ID: NCT07077213