

Study Title: Imaging Cardiac Amyloid Burden: A pilot Study Using F-18 Florbetapir Positron Emission Tomography

NCT Number: NCT01683825

Document Date: January 2018

Analytical Plan

Study Objective(s)

Specific Aim: The *primary aim* of this pilot study is to determine whether amyloid deposits in the heart can be measured non-invasively by F-18 florbetapir (Trade Name: Amyvid) positron emission tomography (PET) in 30 individuals with documented cardiac amyloidosis and in 15 volunteers without cardiac amyloidosis.

A secondary aim of this study is to determine reproducibility of F-18 florbetapir uptake in the myocardium.

Study groups:

Subjects with cardiac amyloidosis and control subjects without cardiac amyloidosis.

Imaging Methods

In this pilot feasibility study, F-18 florbetapir was used to image myocardial amyloid deposits. F-18 florbetapir PET/CT images were acquired in a dynamic mode and reconstructed into static images. Visual assessment and SUV of myocardial uptake of F-18 florbetapir was performed on static images from 4 minutes to 30 minutes. The left ventricular global myocardial F-18 florbetapir images were reviewed in the standard radiological and cardiac imaging planes. We used PMOD software to measure global left ventricular standardized uptake value (SUV) of F-18 florbetapir using SUV mean (SUVmean).

Statistical Methods

This is a pilot feasibility study using F-18 florbetapir to image myocardial amyloid deposits. Mean and maximal myocardial uptake of F-18 florbetapir will be estimated in the subjects with diagnosed cardiac amyloid. Mean liver to heart ratio will be estimated.