

## **Title**

**The incremental diagnostic value of 18F-Florbetapir imaging in naturalistic patients with cognitive impairment: the INDIA-FBP study.**

## **Authors**

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## **Background**

18F-Florbetapir PET tracer has been recently approved by the FDA and EMA for *in vivo* assessment of amyloid pathology in patients undergoing evaluation for Alzheimer's disease (AD) and other causes of cognitive decline. A key advantage of 18F-ligands is their relatively long radioactive half-life (110-min), making it feasible to produce and distribute 18F-amyloid tracers on a large scale.

## **Aim**

To evaluate the incremental diagnostic value of 18F-Florbetapir PET on top of routine assessment

1. for the early diagnosis of AD at the MCI stage
2. for the differential diagnosis of AD from non AD dementias.

## **Methods**

The study started in Sept 2013 and plans to enroll 250 patients coming to observation of 20 Alzheimer's Evaluation Unit (UVA) in Eastern Lombardy, Italy, until Dec-2014. 30 healthy elderly controls (HC) will also be enrolled. Patients will undergo a diagnostic work-up according to usual local practice. Physicians will formulate a clinical diagnosis and rate their diagnostic confidence (range between 15% and 85%). Patients will undergo 18F-Florbetapir PET. Diagnosis and diagnostic confidence will be revised based on 18F-Florbetapir PET results.

## **Preliminary results**

During the first 4 months, 67 patients and 8 HC have been enrolled. Of these, 39 patients completed their diagnostic work-up: 15 had a clinical diagnosis of MCI due to AD; 12 of AD; 4 of FTLD; 4 of MCI not due to AD; and 4 of other dementias (e.g. PD, DLB). 36 patients and 4 HC underwent 18F-Florbetapir PET. Negative scans occurred in 27% of AD, 36% of MCI due to AD, 50% of MCI not due to AD, 33% of FTLD, 25% of patients with other dementias. One HC had a positive amyloid-PET scan. The diagnosis of 30 patients was re-evaluated post-amyloid imaging, and 18F-florbetapir PET results led to a change in diagnosis in 50% of these patients. The diagnostic confidence increased significantly after amyloid imaging for both confirmed and changed clinical diagnoses (17% and 15% increase in confidence respectively,  $p < 0.001$ ).

**Conclusion**

Based on the preliminary results, 18F-Florbetapir PET has a significant impact on diagnosis and diagnostic confidence of dementia experts.