

AMYPAD Deliverable 3.17

Mid-term recruitment report Quarterly report V10

Publishable Summary

End of June 2021 has marked an important step in the finalization of the AMYPAD Diagnostic and Patient Management Study. Indeed, all visits and scanning activities have been completed by sites, in order to provide sufficient time to lead the data cleaning and analysis activities.

With a total of 844 patients randomized on 900 originally planned, DPMS has been able to navigate through a difficult period to deliver sufficient data to satisfy its objective, and especially the primary one: to test the hypothesis that the proportion of participants for whom the managing physician reaches an etiologic diagnosis with very high confidence (≥90%) at 12 weeks after baseline is higher for participants who underwent amyloid PET imaging shortly after baseline than for participants who have not yet undergone amyloid PET imaging.

The dropout rate between baseline visit and week 12 visit was inferior to 5%.

Despite the visits and scanning limitation due to COVID-19, 751 patients attended the 6 months visit (dropout rate= 5.5% from week 12) and 230 underwent the late scan at 8 months. On top of this, 238 free choice scans have been performed to reach a total of 850 amyloid PET scans during the study.

The next and last quarter of the study is now being dedicated the finalization of the data cleaning and analysis to deliver the publication plan. Specifically, an advanced draft of the paper describing enrollment strategies and baseline features of the DPMS cohort has been sent to coauthors and, once all comments are addressed, it will be submitted to Alzheimer's & Dementia. Preliminary analyses on the primary endpoint have been performed, and an initial version of the manuscript has been drafted. However, some amyloid-PET results (visual read) of ARM1 patients have not been entered into the dataset (it will be done by the recruiting memory clinics in the next weeks). This missing information prevents from having a final dataset for analyses.

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