Biomarkers of Sleep-wake Cycle in Prodromal Alzheimer's Disease: Role in Cognitive Decline?

NCT05629871

Status	RECRUITING
Phase	Not Applicable
Sponsor	University Hospital, Montpellier
Enrollment	132 participants

Plain Language Summary

This study is investigating how sleep disturbances relate to the progression of early Alzheimer's disease. Researchers will measure sleep-wake cycle biomarkers (from blood, spinal fluid, and body temperature) alongside cognitive tests to see whether disrupted sleep predicts faster cognitive decline and whether it could serve as an early warning sign.

You may be eligible if...
- You have been diagnosed with mild Alzheimer's disease (MMSE score 21–30)
- You have a family caregiver who can help with questionnaires and diaries
- You have already had, or are scheduled for, a lumbar puncture (spinal fluid test) as part of your standard care
- You are covered by the French social security system

You may NOT be eligible if...
- You have a genetic (hereditary) form of Alzheimer's disease
- You have recently started or changed Alzheimer's medications (unless stable for at least 3 months)
- You are taking antidepressants, sleep medications, or antipsychotics
- You live in a nursing home
- You have medical reasons that prevent a spinal fluid test (such as a clotting disorder, skin infection at the puncture site, or spinal surgery)
- You have severe physical or sensory problems that interfere with testing

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (7)

- Diagnosis of mild Alzheimer's disease with a Mini Mental State (MMS) between 21-30
- The presence of a family carer to complete neuropsychological scales, questionnaires and sleep diaries
- Having a neurological assessment and/or follow-up requiring blood and cerebrospinal fluid (CSF) sampling with biomarkers for diagnostic purposes
- Patient who had a lumbar puncture less than one year ago or patient with a scheduled lumbar puncture as part of care
- Signed informed consent

... and 2 more (see full listing online)

Exclusion (14)

- Genetic form of alzheimer's disease
- Insufficient clinical and paraclinical information for the diagnosis of AD
- Anticholinesterase and/or memantine treatment or on stable doses for at least 3 months
- Use of antidepressants, anxiolytics, hypnotics, neuroleptics, 15 days before inclusion
- Patient living in a nursing home

... and 9 more (see full listing online)

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Locations (3 total)

University Hospital, Montpellier, Montpellier, France
University Hospital of Poitiers, Poitiers, France
University Hospital of Toulouse, Toulouse, France

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