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A Swedish study within the European Platform for Neurodegenerative Diseases (EPND) aiming to identify new biomarkers in dementia

Submission date
24/04/2026

Recruitment status
Recruiting

Registration date
01/06/2026

Overall study status
Ongoing

Last Edited
01/06/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

Study information

Scientific Title
A Swedish, prospective, observational case study within the European Platform for Neurodegenerative Diseases (EPND) aiming to identify new biomarkers in dementia

Study objectives
The primary objective of this project is to enrich the existing real-world memory clinic database and biobank GEDOC at Karolinska University Hospital (KUH) with longitudinal data and sample collection from prospectively enrolled participants.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/05/2025, Etikprövningsmyndigheten (Swedish Ethical Review Authority) (Etikprövningsmyndigheten Box 2110, Uppsala, 75002, Sweden; +46 (0)104750800; registrator@etikprovning.se), ref: Dnr 2025-01621-01

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Cognitive decline

Interventions
The enriched dataset will comprise comprehensive fluid, neuroimaging and digital biomarkers aiming to improve diagnosis and molecular characterization of the earliest stages of Alzheimer's disease and related dementias. Specifically, the GEDOC-EPND study will create a cohort of 300 prospectively enrolled participants from the entire memory clinic population, who will be invited for annual follow-ups over 3 years. This initiative will facilitate the creation of innovative digital biomarkers and multi-marker predictive models for the early detection of cognitive changes, making the findings accessible to other researchers through the EPND platform.

Intervention Type
Other

Primary outcome(s)
1. Discovery of new dementia biomarkers measured using speech biomarkers (digital, part of the VoiceDx project) and Roche Neurotool Kit (fluid, cerebrospinal fluid [CSF] and blood) at yearly assessments (voice recordings every 3 months)

Key secondary outcome(s)

Completion date
31/12/2035

Eligibility

Key inclusion criteria
Research participants who consented to the memory clinic database at Karolinska University Hospital (GEDOC) and who speak and read Swedish

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Moderate dementia and severe dementia, as determined by Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5)
2. Severe visual or communication impairment
3. Conditions that prevent cooperation/participation as determined by the physician
4. A serious illness (e.g., cancer, severe psychiatric/neurological illness [in addition to Alzheimer's disease (AD)]), as determined by the physician's clinical judgment
5. Withdrawn consent to the GEDOC and/or EPND study

Date of first enrolment
27/10/2025

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
Sweden

Sponsor information

Organisation
Karolinska University Hospital

ROR
https://ror.org/00m8d6786

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type

Funder Name

Gates Ventures

Alternative Name(s)
Gates Ventures, LLC, The Gates Notes LLC

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Alzheimer's Drug Discovery Foundation

Alternative Name(s)
Alzheimer's Drug Discovery Foundation, LLC, ALZHEIMERS DRUG DISCOVERY FOUNDATION, The Alzheimer's Drug Discovery Foundation, ADDF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
AD Data Initiative (ADDI)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request, granted prerequisite requirement are met, through the AD Workbench

IPD sharing plan summary
Available on request