

Cohort profile: The ODIN (blood and cerebrospinal fluid) Biobank – a Danish cohort for dementia research

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Word count: 1484

ABSTRACT

Purpose: Biomarkers related to the diagnosis, prognosis, and treatment of dementia will play a key role in future clinical practice. The overarching aim of the ODIN (blood and cerebrospinal fluid) Biobank is to study biomarkers for dementia and contribute to the transition from cerebrospinal fluid to blood-based biomarkers.

Participants: ODIN recruited 451 patients (median age 74 years, 53% females) referred to the Department of Neurology at Aarhus University Hospital, Denmark, for diagnostic assessment of dementia. Enrolment started in March 2020 and ended in July 2025. Patients referred for a lumbar puncture were eligible for inclusion. Cerebrospinal fluid and blood samples (plasma, serum, and buffy coat) were stored at – 80 degrees Celsius. Information about sociodemographic, educational level,

dementia subtype, cognitive test scores, neuroimaging results, hypertension, diabetes, height, weight, alcohol consumption, and smoking were collected.

Findings to date: The most frequent diagnoses were Alzheimer's disease (n=268, 59%), frontotemporal dementia (n=26, 5.8%), and mixed Alzheimer's and vascular disease (n=23, 5.1%). N=82 (18%) were cognitively unimpaired or had mild cognitive impairment, but not dementia. The median Mini Mental State Examination Score was 23 (interquartile range: 20-26) and the median Addenbrooke's Cognitive Examination Score was 68 (interquartile range: 58-77).

Future plans: ODIN will contribute to the development, validation and implementation of new biomarkers related to diagnosis, prognosis, and treatment of dementia. Furthermore, the cohort will assist the transition from cerebrospinal fluid to blood-based biomarkers

Strengths and limitations of this study

- The biobank was established in a routine clinical setting nested in a health care system with free tax-paid access. Thus, the biobank holds information on a real-world heterogeneous patient population with a broad spectrum of dementia subtypes and some without dementia.
- The biobank contains detailed clinical data, cerebrospinal fluid, and blood samples. Neurologists with subspecialty in dementia classified the dementia subtype based on clinical data, neuroimaging, and biomarkers.
- Only patients referred for a lumbar puncture as part of their diagnostic work-up were eligible for inclusion.

- The biobank does not have longitudinal follow-up for primary data collection. However, linkage to Danish national registers will allow us to track patients over time and gather information on hospital diagnoses, medication use, and mortality.

Introduction

Dementia is a growing health concern affecting individuals, societies, and healthcare systems worldwide.¹ The syndrome covers different etiologies, including Alzheimer's disease, Lewy Body disease, vascular disease, and frontotemporal dementia, among others.² With an aging population, the prevalence of dementia will rise, causing a demand for efficient diagnostic work-up and treatment.¹

A variety of underlying pathologies causes dementia, and the diagnostic process is complex and time-consuming.² However, biomarkers are rapidly developing to assist in diagnosis supporting a transition towards biologically defined diagnoses instead of clinical syndromes.^{3,4} For instance, Alzheimer's disease pathology, defined by the accumulation of amyloid- β and hyper-phosphorylated tau (p-tau), can be visualized on positron emission tomography or detected in the cerebrospinal fluid.^{4,5} Accurate dementia diagnosis requires a comprehensive work-up, often involving clinical information, lumbar puncture, and structural and functional neuroimaging. Currently, imaging and cerebrospinal fluid biomarkers are regarded as the gold standard.⁵ However, these methods are invasive, expensive, and not widely available in non-specialized healthcare settings.⁵⁻⁷ A transition to blood-based biomarkers may provide novel, cost-efficient, and minimally invasive opportunities.^{5,6,8-10} Furthermore, disease-modifying treatments for Alzheimer's disease have been approved for clinical use, which motivates early detection.¹¹ Studies suggest that biomarkers will play a key role in early diagnosis and guiding treatment.^{5,6,9,10,12,13} Although

blood-based biomarkers seem promising, more research is needed. For this purpose, a biobank established in a real-world setting with a heterogeneous patient population spanning a broad spectrum of dementia etiologies is warranted. Here, we present a cohort profile and baseline data for the ODIN (blood and cerebrospinal fluid) Biobank.

Cohort description

Objectives

The overall aim of the ODIN Biobank is to study biomarkers of dementia and to contribute to the transition from cerebrospinal fluid to blood-based biomarkers. Specific objectives are:

- To evaluate associations between biomarkers and clinical and neuroimaging data.
- To evaluate associations between blood-based and cerebrospinal fluid biomarkers.
- To estimate diagnostic cut-offs for biomarkers.
- To investigate the prognostic and predictive performance of biomarkers.

Setting and study population

ODIN recruited patients referred to the Department of Neurology at Aarhus University Hospital, Denmark, for diagnostic assessment of suspected dementia. Enrollment started in March 2020 and ended in July 2025. Denmark has a tax-funded healthcare system that ensures free access to healthcare for all residents.¹⁴ General practitioners (primary care physicians) initiate the diagnostic work-up of dementia, which includes obtaining information on medical history and symptoms, performing short cognitive assessment (e.g., tests like the Mini-Mental State Examination or the Brief Assessment of Impaired Cognition), blood tests, and ruling out common alternative diagnoses. If suspicion of dementia persists, patients are referred to the hospital sector. In Denmark (population 6 million), around 9000 individuals are sent for dementia assessment each year. The Department of Neurology at Aarhus University Hospital

evaluates patients from the Central Denmark Region. This region has a unified referral system, directing ~ 1400 patients per year in average to neurological, psychiatric (in case of severe behavioral issues), or geriatric (in case of severe comorbidities) departments throughout the region. In average, the Department of Neurology at Aarhus University Hospital assesses ~ 600 patients annually (~ 45% of patients assessed for dementia in the Central Denmark Region).¹⁵⁻¹⁷ Patients were eligible for inclusion in the ODIN Biobank if they were referred for a lumbar puncture as part of their diagnostic work-up, were able to understand and speak Danish, and could provide informed consent. Approximately 100 patients per year met these criteria and consented to participate (Figure 1). Patients who underwent lumbar puncture were typically < 80 years of age with mild to moderate dementia of uncertain cause and with no contraindications for the procedure.

Data collection

The biobank holds data on age, sex, ethnicity, educational level, dementia subtype, cognitive test scores, neuroimaging results, information on functional capacity, hypertension, diabetes, height, weight, alcohol drinking, and smoking at the time of inclusion (Table 1). Neurologists with subspecialty in dementia or other trained healthcare staff documented information during the first routine visit. Hypertension and diabetes were based on medical history and/or clinical evaluation.

Biobank material and biochemical analyses

A lumbar puncture was performed to collect cerebrospinal fluid in three consecutive 2-mL fractions using polypropylene tubes. The first fraction was discarded. The second fraction was kept at room temperature and centrifugated (2000 G for 10 minutes) within a maximum of two hours and then analyzed for biomarkers related to routine diagnostics (primarily total-tau, phosphorylated-tau181, and amyloid beta 1-42). The third fraction was stored at approximately 6 degrees Celsius for a maximum of 24 hours in case additional testing (e.g., microbiology) was needed. Up to eight aliquots of cerebrospinal fluid (500 µL each) were stored at – 80 degrees Celsius in cryo tubes (Figure 2).

Blood samples were collected in K2 EDTA tubes (1 x 9 mL) and serum tubes (1 x 10 mL) and kept at room temperature until centrifugation. Samples were centrifuged at 2000 G for 10 minutes within two hours. Up to four aliquots of serum, four aliquots of plasma, and one aliquot of buffy coat were stored at -80 degrees Celsius in cryo tubes (500 µL each) (Figure 2).

Potential for linkage to secondary data sources

Denmark has an extensive infrastructure of nationwide, population-based administrative and clinical registries providing an opportunity to collect additional baseline information (e.g. comorbidities, medication use, and laboratory information results) and to follow patients over time concerning hospital-diagnoses, medication use and mortality.¹⁴ Linkage between the ODIN biobank and these registries is possible via the civil registration number assigned uniquely to all Danish residents at birth or emigration. Table 2 shows an overview of selected data sources or registries.^{14 18}

Patient and Public Involvement

It was not appropriate or possible to involve patients or the public in the design, conduct, reporting, or dissemination plans of our research.

Cohort characteristics

We enrolled 451 patients (median age 74 years, 53% females). Of those 451 patients, 82 (18%) were cognitive unimpaired or had mild cognitive impairment, but not dementia. The most frequent diagnoses were Alzheimer's disease (n=268, 59%), frontotemporal dementia (n=26, 5.8%), and mixed Alzheimer's and vascular disease (n=23, 5.1%) (Table 3). The median Mini Mental State Examination Score was 23 (interquartile range: 20-26) and the median Addenbrooke's Cognitive Examination Score was 68 (interquartile range: 58-77). All patients had structural imaging (computer tomography [CT] or Magnetic Resonance Imaging [MRI]) performed. The vast majority had [18F]fluorodeoxyglucose positron emissions tomography (FDG PET), and a minority of patients had [18F]flutemetamol amyloid PET or [18F]FE-PE2I PET of the dopamine system performed (Table 4).

Hypertension was present in 222 (49%) patients, diabetes was present in 55 (12%) patients, 40 (8.9%) had an alcohol intake \geq 15 units/week, and 76 (16%) were current smokers (Table 4).

Findings to date

A share of the biobank has contributed to diagnostic cut-offs for beta-amyloid 1–42, total tau, and phosphorylated tau 181 in the cerebrospinal fluid, which are applicable in the diagnostic work-up of suspected Alzheimer's dementia.⁷

Strengths and limitations

The strengths of the biobank are multiple. The cohort is nested in a universal healthcare system with free access to healthcare services, including dementia assessment. Recruitment occurred in the routine clinical care, ensuring that the cohort reflects a real-world patient population. Additionally, the broad spectrum of dementia etiologies facilitates a head-to-head testing of biomarkers of specific pathology against each other. The biobank contains detailed clinical data and neuroimaging results together with paired cerebrospinal fluid and blood samples. Neurologists with a subspecialty in dementia evaluated dementia subtypes based on a combination of clinical data (cognitive test scores), neuroimaging, and biomarkers. The pre-analytical phases were standardized and performed by trained personnel, thereby ensuring the quality of the biobanked materials. Consequently, biomarkers can be correlated with clinical diagnoses and results from neuroimaging and blood-based biomarkers can be compared to gold-standard biomarkers in cerebrospinal fluid or imaging as well as clinical information, thereby supporting the transition to blood-based biomarkers.

The biobank also has limitations. First, inclusion was restricted to patients referred to lumbar puncture, which were typically individuals under 80 years of age with mild to moderate dementia of uncertain origin and without contraindications for the procedure. Furthermore, patients with early onset dementia were few and 99% of the population were Caucasian. This selection may limit generalizability or introduce selection bias, depending on the research question. Biomarker cut-offs derived from this cohort

should therefore be interpreted within the context of the study population. Second, although we did collect information on education and some clinical data (e.g. diabetes and hypertension), other relevant information on socioeconomics and comorbidities may be missing. Last, we did not have longitudinal follow-up through primary data collection. Nonetheless, linkage to Danish national registers will allow us to collect additional baseline data and track patients over time regarding hospital diagnoses, medication use, and mortality.

Collaboration

The steering committee invites public researchers to contact them or the corresponding author for collaboration. Data and sample material from the ODIN Biobank are available on reasonable request and upon obtaining the necessary permissions.

Authors' contributions: HG, PB, TP, and HJM conceived the project idea and are responsible for the implementation of the biobank. HG and PB are responsible for data collection and TP and HJM responsible for the biobank. CS is responsible for data management. KL wrote the initial draft, and HG, PB, TP, HJM, CS, and NO revised it critically. KL is the guarantor.

Funding statement: The Department of Clinical Biochemistry, Aarhus University Hospital, Denmark, support this work. The funders had no role in the study design; in the collection, analysis and interpretation of the data; in the writing of the report; and in the decision to submit the paper for publication. The funder didn't influence the results/outcomes of the study despite author affiliations with the funder.

Competing interest statement: Authors declare no conflict of interests. The funder didn't influence the results/outcomes of the study despite author affiliations with the funder.

Ethics: Data collection and presentation of baseline data in this protocol have been approved by the Danish Data Protection Agency (1-16-02-677-16 and 1-16-02-355-24, respectively). All patients receive verbal and written information before enrolment and give oral and written consent at baseline according to the guidelines from the Danish Ethics Committee. All patients are informed that they can withdraw from the study without affecting their treatment. In case of withdrawal, samples are discarded, and all patient-related registrations are deleted from the biobank. The project is conducted in accordance with the Declaration of Helsinki. It was deemed inappropriate or impossible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research. The Ethics Committee, Central Denmark Region, exempted this cohort. Future studies using data from the biobank may need additional approval by the Danish Ethics Committee and/or the Danish Data Protection Agency, depending on type of data needed for the specific project.

Acknowledgements: The authors wish to acknowledge Lene Damm Christensen for laboratory assistance and Michael Gejl Jensen for his initial work with the biobank. Henriette Klit, Janne Mortensen, Vivi Brandt and Stine Trærup Vad for data entry and Joel F. A. Aanerud and Allan K. Hansen for neuroimaging data collection, reporting, and data entry.

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FIGURES

Figure 1. Setting and study population. The Department of Neurology at Aarhus University Hospital evaluates patients from the Central Denmark Region (covering ~ 1.3 million people). This region has a unified referral system, directing patients to neurological, psychiatric, or geriatric departments throughout the region. *Patients who were referred for a lumbar puncture as part of their diagnostic work-up for dementia and understand, read, and speak Danish were eligible for inclusion in the ODIN Biobank. Created in BioRender.

Figure 2. Standard operating procedures in the ODIN Biobank. CSF, cerebrospinal fluid. Created in BioRender.

Table 1. Overview of data in the ODIN Biobank

| Type | Description |
|----------------------------------|--|
| Demographic and educational data | Personal identification number, date of birth, sex, ethnicity, and educational level (years of education) |
| Cognitive tests and scores | Mini-Mental State Examination and Addenbrooke's Cognitive Examination |
| Clinical data | Dementia diagnosis, height, weight, diabetes (yes, no), hypertension (yes, no) |
| Lifestyle-related data | Smoking (current, former, never), alcohol consumption per week (< 15 units, ≥ 15 units, undisclosed) |
| Functional capacity | Activity of Daily Living score |
| Biological specimens | Plasma, serum, buffy coat, cerebrospinal fluid |
| Immediate biochemical analyses | Biomarkers in cerebrospinal fluid: Total-Tau, phosphorylated-tau181, amyloid beta 1-42, and neurofilament light chain* |
| Imaging** | MRI, CT, FDG-PET, amyloid-PET, PE2I-PET |

CT, computer tomography; MRI, Magnetic resonance imaging; FDG-PET, fluorodeoxyglucose positron emissions tomography.

*Only when relevant.

**Type of imaging performed depends on clinical evaluation.

Table 2. Overview of selected secondary data sources or registries

| Data source | Description | Selected variables |
|-------------------------------|--|---|
| The Civil Registration System | Nationwide, covering the entire population since 1968. | Civil registration number Date of birth Sex |

| | | |
|---|--|---|
| | | Date of immigration Date of emigration Date of dying |
| The Business Intelligence Portal | Central Denmark Region, covering all inpatient, outpatient and emergency department contacts since 2012, all laboratory data from 2008, and all medication since 2019. | Civil registration number of patient Date of admission and discharge Diagnostic codes Procedure codes Medication Biochemical data |
| The Danish National Patient Registry | Nationwide, covering all non-psychiatric inpatient hospitals contacts since 1977 and all psychiatric inpatients, emergency department and outpatient contacts since 1995 | Civil registration number of patient Date of admission and discharge Diagnostic codes Procedure codes |
| The Danish National Prescription Registry | Nationwide, covering all outpatient pharmacies since 1995. | Civil registration number of patient Date of filled prescription Medication type Number of tablets/injections etc. Dose per pill/injection etc. Number of prescriptions Defined daily dose Formulation |
| The Danish Register of Causes of Death | Nationwide, covering all deaths since 1973. | Civil registration number Date of dying Manner of death Cause of death |
| The Danish National Laboratory Database | Nationwide with complete coverage since 2015. | Civil registration number of patient NPU codes Date of request Biomarker result and unit Laboratory code Reference interval or cut off |

Notes: Denmark has a large infrastructure of nationwide, population-based administrative and clinical registries. Linkage between the ODIN biobank and these registries is possible via the civil registration number assigned unique to all Danish residents at birth or emigration. Abbreviations: NPU, the International System of Nomenclature, Properties, and Units.

References: Schmidt M, Schmidt SAJ, Adelborg K, et al. The Danish health care system and epidemiological research: from health care contacts to database records. *Clin Epidemiol.* 2019;11:563-591 and Laugesen K, Mengel-From J, Christensen K, et al. A Review of Major Danish Biobanks: Advantages and Possibilities of Health Research in Denmark. *Clin Epidemiol.* 2023;15:213-239.

Table 3. Demographics and diagnoses of patients enrolled in the ODIN Biobank from March 2020 to July 2025

| | N (%) |
|-------------------|------------|
| Total | 451 (100) |
| Demographics | |
| Age, median (IQR) | 74 (69-78) |

| | |
|---|----------|
| Male | 212 (47) |
| Female | 239 (53) |
| Education | |
| < 8 years of school | 57 (13) |
| Elementary school | 79 (18) |
| Short-cycle (< 3 years) higher education | 134 (30) |
| Medium-cycle (3-4 years) higher education | 121 (27) |
| Long-cycle (> 4 years) higher education | 55 (12) |
| Missing | 5 (1.1) |
| Ethnicity | |
| Caucasian | 445 (99) |
| Other | 1 (0.2) |
| Missing | 5 (1.1) |
| Diagnosis | |
| Alzheimer's disease | 268 (59) |
| Frontotemporal dementia | 26 (5.8) |
| Mixed Alzheimer's and cerebrovascular disease | 23 (5.1) |
| Lewy Body dementia | 15 (3.3) |
| Cerebrovascular disease | 21 (4.7) |
| Atypical Parkinson disease | 8 (1.8) |
| Alcohol-related disorder | 7 (1.6) |
| Non-neurodegenerative disease | 12 (2.7) |
| Other specific dementia | 7 (1.6) |
| Normal pressure hydrocephalus | 1 (0.2) |
| Psychiatric disorders | 1 (0.2) |
| Undecided | 49 (11) |
| Missing | 12 (2.7) |
| Dementia severity | |
| Mild | 260 (58) |
| Moderate | 101 (22) |
| Severe | 2 (0.4) |
| Not dementia, but cognitive impaired | 74 (16) |
| Cognitive habitual | 8 (1.8) |
| Missing | 5 (1.1) |

Notes: Data were collected by neurologists with subspecialty in dementia or trained health care staff. Neuroimaging is described by medical specialists in nuclear imaging.

Table 4. Clinical characteristics of patients enrolled in the ODIN Biobank from March 2020 to July 2025

| | N (%) |
|---|------------|
| Total | 451 (100) |
| Cognitive test scores | |
| Mini-Mental State Examination, median (IQR) | 23 (20-26) |
| Missing | 5 (1.7) |

| | |
|---|------------|
| Addenbrooke's Cognitive Examination, median (IQR) | 68 (58-77) |
| Missing | 9 (2.0) |
| Neuropsychological evaluation performed | 139 (31) |
| Activity of daily living score, median (IQR) | 11 (7-16) |
| Missing | 5 (1.7) |
| Imaging (yes), N | |
| MRI | 202 (45) |
| CT | 281 (62) |
| FDG-PET | 414 (92) |
| Amyloid-PET | 28 (6.2) |
| PE2I-PET | 18 (6.0) |
| Comorbidities* | |
| Diabetes | 55 (12) |
| Hypertension | 222 (49) |
| Lifestyle-related factors | |
| Body Mass Index (kg/m ²) | |
| <18.5 | 16 (3.6) |
| 18.5-25 | 206 (46) |
| 25-30 | 150 (33) |
| >30 | 66 (15) |
| Missing | 13 (2.9) |
| Alcohol intake (units/week) | |
| <15 | 397 (88) |
| ≥ 15 | 40 (8.9) |
| Undisclosed | 9 (2.0) |
| Missing | 5 (1.1) |
| Smoking, N (%) | |
| Current | 73 (16) |
| Former | 178 (39) |
| Never | 186 (41) |
| Undisclosed | 9 (2.0) |
| Missing | 5 (1.1) |

Notes: Data were collected by neurologist with subspecialty in dementia or trained health care staff. Neuroimaging was described by medical specialists in nuclear imaging.

*Reported by medical doctors based on medical history and clinical evaluation.

CT, computer tomography; MRI, Magnetic resonance imaging; PET, Positron Emissions Tomography.