



Our study centre is at **The National Hospital for Neurology and Neurosurgery (NHNN), Queen Square, London WC1N 3BG**

Nearest mainline train stations: London Euston and King's Cross St Pancras

Nearest tube stations: London Euston, King's Cross, Russell Square, Euston Square, and Holborn

Getting involved...

If you are interested in participating in our clinical trials or other research, please email our recruitment team at

drctrialenquiries@ucl.ac.uk

The DRC also actively supports <u>Join Dementia Research</u>, which matches participants to appropriate research studies throughout the UK.



www.ucl.ac.uk/drc/research/clinical-trials

Drug trials at the DRC



The Clinical Trials Team is led by **Dr Cath Mummery** and runs a number of clinical trials. These treatment trials are vitally important to allow us to develop and test medicines that may slow the progression of diseases causing dementia, or even prevent the onset of symptoms. Most clinical trials involve a number of visits to our clinic to measure the safety and effects of the drug over time. To find out more about what is involved in taking part in a clinical trial at the DRC, please visit our website at <u>www.ucl.ac.uk/drc/</u><u>research/clinical-trials/what-do-trials-involve</u>

Why do we do clinical trials?

- To test whether a new drug can slow disease progression and have beneficial effects on symptoms of dementia
- > To monitor safety and any potential side-effects
- To asses the effects of a new drug on other indicators of disease progression e.g. levels of amyloid or tau in the brain
- Most studies are "randomised placebo-controlled trials": participants are randomly assigned to one of two main groups: active drug administration or placebo (no active drug) administration. Neither the participant nor the study team will know which group they have been assigned to during the trial.
- Most of our drugs (or placebos) are administered orally, by subcutaneous or intramuscular injections, via intravenous infusion, or via lumbar puncture.

Contact us...

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DEMENTIA RESEARCH CENTRE

If you have any questions or would like more information, please get in touch with our Clinical Trials Team by emailing us at <u>drctrialenquiries@ucl.ac.uk</u>

You can also contact us by telephone during office hours (9-5, Mon-Fri) on **020 3448 3105**

DISCLAIMER: We aim to ensure that all information is as accurate as possible, but we accept no responsibility for any errors, omissions or inaccuracies. Please see the clinician responsible for your care, a social services representative, or your GP if you have specific needs which require attention. Any medical decisions should be taken in discussion with an appropriate health care professional.

Ongoing trials (closed to recruitment)

- ACI-35-182: A phase 1b/2a study evaluating safety and side effects of anti-tau vaccines in early AD
- INVOKE (AL002-2): A phase 2 study evaluating safety and efficacy of an antibody targeting the immune system in early AD
- DESPIAD: A phase 2b trial investigating the safety and efficacy of miridesap, a drug which reduces a protein called Serum Amyloid P Component, in mild AD
- INFRONT-2 (AL002-2) and INFRONT-3 (AL001-3): phase 2 and phase 3 studies assessing the effects of increasing progranulin using the antibody drug AL001 on slowing disease progression and the onset of symptoms in progranulin gene mutation carriers with or at risk of FTD.
- EISAI (E2814-G000-301): A phase 1b/2 study assessing safety and target engagement of the antibody drug E2814, which reduces accumulation of tau in the brain and enhances its clearance, in patients with Dominantly Inherited Alzheimer's Disease (DIAD)

Coming soon...

- A phase 1b anti-tau gene silencing trial looking at the effects of drug on tau production and clearance in AD and DIAD
- A phase 2b trial of a diabetes drug in participants at risk of AD
- A phase 1b/2a anti-amyloid antibody trial in patients with mild to moderate AD



ImmunoBrain (IBC-01-01)

We are recruiting!

Official title

A first in human study (Phase I) to evaluate the safety, tolerability and pharmacokinetics of IBC-Ab002 in persons with early Alzheimer's disease (AD).

Purpose of the study

To investigate the safety (side effects) of a new drug, IBC-Ab002, in patients with early AD. IBC-Ab002 is an antibody which may help suppress age-related immune system decline by blocking certain immune system pathways that cause age-related impairment, slowing progression of AD.

Participants

Patients with a diagnosis of early Alzheimer's disease (AD), with a MMSE score of 20-28, who are between 50 and 80 years of age. Participants must be in good general health, other than AD.

What is involved?

This study will be carried out in 2 parts; *Part A* and *Part B*. In *Part A*, a single dose of study medication is given. *Part B* will begin approximately 3 months later, and 3 doses of study drug will be given 3 months apart. The drug or placebo is administered via IV infusion. Total participation in this study will include approx. 23 visits to the study site over a period of just over a year. Participants will visit us for drug/placebo administration, and also for assessments including medical and neurological examinations, memory and thinking questionnaires, blood and urine tests, brain scans (MRI and PET), and lumbar puncture.

Biogen CELIA (BIIB080)

We are recruiting!

Official title

A randomized, double-blind, placebo-controlled, parallel-group study to assess the efficacy, safety, and tolerability of BIIB080 in subjects with Mild Cognitive Impairment (MCI) due to Alzheimer's disease or mild Alzheimer's disease dementia (Phase II)

Purpose of the study

BIIB080 has been shown to inhibit the production of Tau protein in the brain. By comparing various dosing regimes of BIIB080 with a placebo, Biogen are investigating if reducing tau production will slow down the progression of cognitive dysfunction in patients with early Alzheimer's disease (AD). They will also be assessing safety and side effects.

Participants

Patients with a diagnosis of early AD (MCI and mild AD), with a MMSE score of 22-30, who are between 50 and 80 years of age. Participants must be in good general health, other than AD.

What is involved?

Participants will make up to 18 visits to the study site over the course of the study. Initially there will be 3 screening visits over 9 weeks. If screening is successful, participants will enter the 18 month treatment phase of the trial and randomise to one of the BIIB090 dosing regimes or placebo. Drug/placebo will be administered every 12 weeks via lumbar puncture and there will be additional assessment visits. Assessments will include regular medical examinations, blood tests, urine tests, brain imaging (PET and MRI), and completion of memory and thinking questionnaires. Following the treatment phase there will be a 5 month follow-up phase which will include 1 visit to the study site and 1 phone call.



DIAN-TU-001 (E2814 Secondary Prevention *Tau NexGen*)

We are recruiting!

Official title

A Phase II/III multicenter randomized, double-blind, placebocontrolled platform trial of potential disease modifying therapies utilizing biomarker, cognitive, and clinical endpoints in Dominantly Inherited Alzheimer's Disease

Participants

Patients who have Dominantly Inherited Alzheimer's Disease (DIAD) and are -10/+10 years from age of onset. Participants must know that they are gene positive because there will be open-label administration of lecanemab. Participants must also have a CDR global score of 1 or less.

What is involved?

There are 2 cohorts:

Cohort 1 is for *symptomatic* gene carriers. Participants will start on lecanemab which will be administered via IV infusion every 2 weeks. After 6 months, participants will additionally be dosed with the trial drug E2814 or a placebo, administered via IV every 4 weeks.

Cohort 2 is for *asymptomatic* gene carriers. Participants will start on the trial drug E2814 or a placebo administered via IV every 4 weeks. After 1 year, lecanemab will additionally be administered via IV every 2 weeks.

The study duration is 4-7 years and continues until the last participant who joins the study has reached the end of year 4. Participants will visit us for drug/placebo administration, and also for assessments including medical and neurological examinations, memory and thinking questionnaires, blood and urine tests, brain scans (MRI and PET), and lumbar puncture.



Alnylam-EOAD (ALN-APP-001)

Recruitment paused

Official title

A Phase I study to evaluate the safety and tolerability of ALN-APP in patients with early onset Alzheimer's disease (AD)

Purpose of the study

To evaluate the safety (side effects) of a drug called ALN- APP. This drug may have the potential to slow disease progression by reducing production of amyloid protein, which builds up in the brains of people with AD

Participants

Patients with a diagnosis of early onset AD (onset <65 years), with a MMSE score of 21+, who are over the age of 18. Participants must be in good general health, other than AD.

What is involved?

In Part A of the study, participants will make a total of approx. 18 visits over a period of just over a year. Each visit will take approx. 3 to 6 hours depending on the procedures completed at each visit. An overnight stay may also be required. If a participant passes screening, a single dose of ALN-APP or placebo is administered, and they are closely monitored for several months afterwards. Assessments include medical and neurological examinations, memory and thinking questionnaires, blood and urine tests, brain scans (MRI and PET), and a lumbar puncture.

Part B will be a multi-dose open-label period including patients previously enrolled in Part A, as well as new participants. This will involve multiple administrations of ALN-APP (all patients will receive the active drug and there will be no placebo). The estimated duration of Part B for each participant is up to 2 years, including a 12 month dosing period (7 separate visits) and 6-12 month follow-up period (at least 2-3 visits).