

Evaluating the effects of the novel GLP1 analogue, Liraglutide, in patients with Alzheimer's Disease (ELAD study)

Submission date 18/11/2013	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 18/11/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 13/06/2024	Condition category Mental and Behavioural Disorders	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Alzheimer's disease (AD) is a devastating progressive neurodegenerative disease which affects 10% of people over 65 rising to 40% of those over 85 years, and is a major global healthcare burden. About 820,000 people in the UK and almost 35 million people worldwide live with dementia. Dementia costs the UK economy £23 billion per year, and US\$604 billion worldwide. Liraglutide is already licensed for the treatment of diabetes and has shown promising results in studies carried out in animal models for AD. The aim of this study is to assess the safety and effectiveness of liraglutide in people with AD.

Who can participate?

Men and women aged between 50-85 years and diagnosed with Alzheimer's disease.

What does the study involve?

Participants will be randomly allocated to receive either liraglutide or an identical matching placebo (dummy). Brain scans of all patients will be performed at the Imperial College Clinical Imaging Facility (Hammersmith Campus) at the start of the study and after 12 months treatment with liraglutide or placebo.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

The study is led by Imperial College London and will be conducted at five major universities/sites in the UK.

When is the study starting and how long is it expected to run for?

The study opened to recruitment in December 2013 and will run for 3 years.

Who is funding the study?
Alzheimer's Society UK, Alzheimer's Drug Discovery Foundation, Van Geest Foundation and King's BRC, Novo Nordisk A/S.

Who is the main contact?
Dr Paul Edison
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2013-000962-13

ClinicalTrials.gov (NCT)
NCT01843075

Protocol serial number
14887

Study information

Scientific Title
Evaluating the effects of the novel GLP1 analogue, Liraglutide, in patients with Alzheimer's Disease (ELAD study): a randomised, double-blind, placebo-controlled trial

Acronym
ELAD

Study objectives
Liraglutide is effective in the treatment of Alzheimer's Disease (AD).

More details can be found at: <http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=14887>

Ethics approval required

Old ethics approval format

Ethics approval(s)

London Riverside REC, 06/09/2013, ref: 13/LO/0699

Study design

Interventional 12-month multicentre randomised double-blind placebo-controlled Phase IIb treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Dementia; Disease: Alzheimer's Disease

Interventions

Patients will be randomised on a 1:1 ratio to receive liraglutide (1.8 mg daily by subcutaneous injection) or identical matching placebo.

Liraglutide (Victoza) daily subcutaneous injection for 12 months.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Liraglutide

Primary outcome(s)

Change in cerebral glucose metabolic rate; Timepoint(s): from baseline to follow up at 12-months

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/06/2024

Eligibility

Key inclusion criteria

1. Male/female aged 50-85
2. Capable of giving and capacity to give informed consent
3. A carer who can act as a reliable study partner
4. Diagnosis of probable Alzheimer's disease according to NIAAA criteria
5. Mini-Mental State Examination (MMSE) score of ≥ 22
6. Rosen Modified Hachinski Ischemic score ≤ 4
7. On stable medication for 3 months on or off cholinesterase inhibitors
8. Fluency in English and evidence of adequate premorbid intellectual functioning.
9. Likely to be able to participate in all scheduled evaluations and complete all required tests.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

1. Any contraindications to the use of Liraglutide as per the Summary of Product Characteristics (hepatic impairment, renal impairment with CKD stage 3 and above, inflammatory bowel disease).
2. Significant neurological disease other than AD that may affect cognition.
3. MRI/CT showing unambiguous aetiological evidence of cerebrovascular disease with regards to their dementia.
4. Diabetes mellitus.
5. Currently taking or having taken memantine on the 30 days prior to screening.
6. Current presence of a clinically significant major psychiatric disorder (e.g. Major Depressive Disorder) according to the criteria of the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV).
7. Current clinically significant systemic illness that is likely to result in deterioration of the patients condition or affect the patients safety during the study.
8. History of seizures, excluding febrile seizures in childhood.
9. Treatment with immunosuppressive medications (e.g. systemic corticosteroids) within the last 90 days (topical and nasal corticosteroids and inhaled corticosteroids for asthma are permitted) or chemotherapeutic agents for malignancy within the last 3 years.
10. Myocardial infarction within the last 1 year.
11. History of cancer within the last 5 years.
12. Other clinically significant abnormality on physical, neurological, laboratory, examination that could compromise the study or be detrimental to the patient.
13. History of alcohol or drug dependence or abuse within the last 2 years.
14. Current use of anticonvulsant, anti-Parkinsons, anticoagulant (excluding the use of aspirin 325 mg/day or less) or narcotic medications.
15. Use of experimental medications for AD or any other investigational medication or device within 60 days. Patients who have been involved in a monoclonal antibody study are excluded unless it is known that they were receiving placebo in that trial.

16. Women of childbearing potential. Women who could become pregnant will be required to use adequate contraception throughout the trial.
17. Patients with a personal or family history of medullary thyroid carcinoma (MTC) and patients with multiple endocrine neoplasia type 2 (MEN2).

Date of first enrolment

01/12/2013

Date of final enrolment

01/03/2016

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Hammersmith Hospital

London

United Kingdom

W12 0NN

Sponsor information

Organisation

Imperial College of Science, Technology and Medicine (UK)

ROR

<https://ror.org/041kmwe10>

Funder(s)

Funder type

Charity

Funder Name

Alzheimer's Society

Alternative Name(s)

alzheimerssoc

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Funder Name

Alzheimer's Drug Discovery Foundation (UK)

Funder Name

Van Geest Foundation and King's BRC (UK)

Funder Name

Novo Nordisk

Alternative Name(s)

Novo Nordisk Global

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Denmark

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/04/2019	10/04/2019	Yes	No

