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

Submission date	Recruitment status	[X] Prospectively registered
18/11/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/11/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/06/2024	Mental and Behavioural Disorders	[ ] 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
memory@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Kathy Bouanane

Contact details
Neurology Imaging Unit
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0NN
-
k.bouanane@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number
2013-000962-13

IRAS number

ClinicalTrials.gov number
NCT01843075

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/03/2013

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

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 206; UK Sample Size: 206; Description: 103 subjects per group (liraglutide and placebo) is the planned sample size

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
England

United Kingdom

Study participating centre
Hammersmith Hospital
London
United Kingdom
W12 0NN

Sponsor information

Organisation
Imperial College of Science, Technology and Medicine (UK)

Sponsor details

School of Medicine
Hammersmith Hospital
Du Cane Road
London
England
United Kingdom
W12 0HS

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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
HRA research summary			28/06/2023	No	No