ISRCTN12910557 https://doi.org/10.1186/ISRCTN12910557

Testing the safety and effects of a new drug (GLP-06) in adult subjects (GLP1-06 – first doses in humans)

Submission date
30/11/2022

Recruitment status
Stopped

Registration date
12/06/2023

Overall study status
Stopped

Last Edited
21/03/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
This is a study of GLP-06 (the study medicine), an experimental new medicine for treating obesity. Obesity is a common problem and can lead to some serious and potentially life-threatening conditions, such as heart disease, type 2 diabetes and stroke. GLP-06 is similar to a natural occurring hormone in the body called glucagon like peptide 1 (GLP1). We hope GLP1-06 will work by reducing appetite, so people feel fuller and less hungry. We hope this will help people eat less food and reduce their body weight.

Who can participate?
This is a 2-part study (Parts A and B) in men who are overweight or obese, aged 18 – 70 years.

What does the study involve?
We'll test single and repeated doses of GLP-06, given by slow injection under the skin. We aim to find out its side effects and blood levels, and its effect on food intake, body weight, and how the body handles glucose (a type of sugar).

In Part A we'll test single doses of GLP1-06 or placebo, in up to 6 groups (30 participants in total). The study medicine has never been given to humans before, so we'll start with a small dose, and increase it as the study progresses. Participants in Groups 1–6 will have 1 study session and take up to about 3 weeks to finish the study. They'll stay on the ward for 4 nights in a row and make up to 3 outpatient visits.

In Part B we'll test repeated doses of GLP1-06 or placebo (up to 5 doses over 5 weeks), in up to 3 groups (24 participants in total). Participants will take up to 10 weeks to finish the study. They'll stay on the ward for up to 5 nights in a row on 1 occasion and up to 2 nights in a row on up to 4 occasions, and make up to 6 outpatient visits.

What are the possible benefits and risks of participating?
Benefits:
There will be no benefits to participants in the study.

Risks:
To date, no humans have taken GLP-06, so its side effects are unknown. The study medicine has been thoroughly tested in laboratory animals. The highest dose we can test in this study is one that we predict will give blood levels of the study medicine that were safe in animals.
Other medicines similar to the study medicine have given to many people. The most common side effects are feeling sick (nausea), being sick (vomiting), diarrhoea, and constipation. As nausea and vomiting are expected to be the most common side effects, anti-emetics (anti-sickness medicine) will be available at the clinical unit.
In this study, we'll monitor the participants closely, and we won't increase the dose of GLP-06 unless the previous dose causes no important side effects.
Like other similar medicines, reactions can occur at or near the site of injection. Symptoms might include redness, tenderness, itching and discomfort. Rarely, the study medicine might cause an allergic reaction, and result in more serious symptoms such as breathing difficulty, rash or low blood pressure up to 24 h after the dose. We'll monitor participants closely, to make sure they haven't had a reaction. If they do have a reaction, we'll give appropriate medicine, as needed.

Where is the study run from?
HMR London (UK)

When is the study starting and how long is it expected to run for?
November 2022 to April 2024

Who is funding the study?
Imperial College London (UK)

Who is the main contact?
Dr Malcom Boyce, rec@hmrlondon.com

Contact information

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Scientific

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Clinical Trials Information System (CTIS)
2022-003227-18

Integrated Research Application System (IRAS)
1006364

Protocol serial number
2022/GLP-06/01

Study information

Scientific Title
A randomised, placebo-controlled first in human study to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of GLP1-06 in adult subjects

Acronym
GLP-06 - first doses in humans

Study objectives
Primary objectives:
1. To find out if GLP-06 has any important side effects when given as a single dose to overweight or obese, but otherwise healthy, men.
2. To find out if GLP-06 has any important side effects in overweight or obese men, who either have a normal tolerance to sugar, are prediabetic, or suffer from Type 2 diabetes, when given as repeated doses.

Secondary objective:
1. To find out how much GLP-06 is absorbed into the bloodstream, and how long the body takes to get rid of it, when given as a single dose and repeated doses.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approval pending, South Central – Oxford A (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 104 8061; oxforda.rec@hra.nhs.uk), ref: 22/SC/0459

Primary study design
Interventional

Study design
Interventional double blind randomized parallel group crossover placebo controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity

Interventions
Subjects will be randomised to GLP-06 or placebo, administered by subcutaneous (SC) injection. Allocation to treatment will be according to a predetermined random order.

The trial will be in 2 parts: Part A is a double-blinded, randomised, placebo-controlled, single ascending dose study (SAD), with the exception of cohort 1 which is partially blinded. These subjects will be overweight/obese but otherwise healthy volunteers. The planned starting dose is 0.04 mg.

Part B is a double-blind, randomised, placebo-controlled, multiple ascending dose (MAD) study in sequential groups of male subjects. These subjects will have either normal glucose tolerance, prediabetes or Type 2 diabetes.
Subjects in Part B will receive up to 5 doses of GLP-06/placebo by SC injection over a 29-day period, and have 5 inpatient stays, with a final follow up visit 4-6 weeks post last dose.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
GLP-06

Primary outcome(s)
Safety and tolerability will be assessed by the following measures:
1. Incidence and severity of adverse events (AEs) monitored continuously throughout the study
2. Changes in vital signs (blood pressure, pulse rate, temperature), 12-lead ECGs, physical examination, bedside glucose monitoring and local tolerability assessment to be monitored over the study period
3. Changes in clinical laboratory safety results monitored over the study period

Key secondary outcome(s)
To evaluate the pharmacokinetic parameters (plasma) of single and multiple doses of GLP-06:
1.1. Part A: In each TP, blood samples will be collected often during Day 1, on Days 2, 3, 4, and at each OP and at FU.

1.2. Part B: In each TP, blood samples will be collected often during dosing days, on Day 30, on OP visits, and at FU visit.

Completion date
03/04/2024

Reason abandoned (if study stopped)
The study was stopped by the Sponsor for business reasons (acquisition by U.S. company) and not due to safety findings.

Eligibility

Key inclusion criteria
1. Male non-smokers aged 18-70 years; body mass index 23 - 45 kg/m²
2. Healthy volunteers (Part A)
3. For part B only: either healthy volunteers, or those diagnosed with prediabetes or impaired glucose tolerance or impaired fasting glucose or type 2 diabetes but otherwise in good health, as judged by medical history, medical examination, vital signs, ECG and clinical laboratory tests; able to communicate with study personnel
4. Reliable, willing, and likely to comply with the protocol; willing to comply with the contraception and sperm donation requirements of the protocol.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Male

Key exclusion criteria
1. Not healthy (clinically significant abnormality in our screening tests, which include ECG, vital signs, physical examination, and laboratory safety tests of blood and urine);
2. Abuse or have abused alcohol or drugs in the last 2 years;
3. Have been treated by a doctor for severe allergic disease (such as severe asthma, or severe hayfever requiring regular treatment)
4. Currently taking certain medicines to treat diabetes;
5. Taken prescription medicine during the 14 days before dosing; For Part B participants who are stably treated for their diabetes with certain therapy are allowed;
6. Taken other medicine (except paracetamol or vitamins), herbal remedies or dietary

supplements during the 7 days before first dose;
7. Have clinically relevant surgical history;
8. Have had a serious reaction to any medicine;
9. Have had pancreatitis or pancreatic cancer,
10. Have acute gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea, heartburn) at screening or admission
11. Have had any condition or operation that might affect the way the body absorbs medicines;
12. Have had any clinically significant disease;
13. Taken GLP-06 in the past
14. Are vegans, or have any significant non-religious dietary restriction which will impact the trial;
15. Mental illness might compromise consent;
16. Have history or have abnormal eating behaviour as observed through the Dutch Eating Behaviour (DEBQ) and SCOFF questionnaires at screening;
17. Unwilling to comply with the contraception requirements of the protocol — because of the potential risk to babies conceived during the study;
18. Have donated plasma in the 7 days before screening, or blood in the 3 months before screening, or platelets in the 6 weeks before screening; have taken part in another clinical trial within 3 months before the first admission or are in the follow up period of a clinical trial (where the last dose was taken more than 3 months before);
19. Objection by GP on medical grounds — because they might increase the risk, or confound the assessment of GLP-06;
20. Have had or family history of medullary thyroid carcinoma or multiple endocrine neoplasia type 2
21. Have had an episode of hypoglycaemia
22. Who have a history of diabetic retinopathy

These criteria are designed to select healthy participants, who are robust enough to recover quickly from any adverse effects of GLP-06. We'll study overweight and obese participants because they are the target population for the study medicine.

Date of first enrolment
13/06/2023

Date of final enrolment
11/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
HMR
Cumberland Avenue
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NW10 7EW

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
University/education

Funder Name
Imperial College London

Alternative Name(s)
Imperial College of Science, Technology and Medicine, Imperial College London, UK, Imperial College London, London, England, Imperial College London in United Kingdom, imperialcollege, ICL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary
Not expected to be made available