

Liraglutide and the management of overweight and obesity in people with schizophrenia

Submission date 29/11/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/03/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/05/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

People with schizophrenia die 10- 20 years earlier than the general population. This is in part due to the fact that they are two times more likely to be overweight. One reason for this is the drugs they need to take to control their symptoms. Current approaches to reducing weight in people with severe mental illness have not been shown to be effective for this population in NHS settings. Liraglutide is a drug which is similar to a hormone found in the body that reduces appetite. It is used as a treatment in type 2 diabetes and at a high dose it is also used for weight loss. It is a daily injectable medication. The aim of this study is to see if it is possible to run a study using liraglutide in people with severe mental illness who are overweight.

Who can participate?

People aged over 18 with schizophrenia, schizoaffective disorder or first episode psychosis who have been on antipsychotic medication for a minimum of one month and are either obese or overweight

What does the study involve?

Eligible participants are randomly allocated to either liraglutide or placebo (dummy drug) daily for 6 months. Data is collected at the start of the study and after 12 and 26 weeks on all aspects of running the study, including signing people up to the study, the consent process, if people take the drug during the study, and how many people drop out. Participants are also interviewed about their involvement. All of this information would then be used in the design of the final study to see if liraglutide causes a significant amount of weight loss.

What are the possible benefits and risks of participating?

The trial medication may help participants to lose weight and this may improve health and sense of wellbeing. People involved in the study will have to give an injection each day. Occasionally this can cause a little discomfort or swelling. The researchers will carefully explain how to use the injection pen to reduce the likelihood of this happening and give a leaflet containing this information. There may also be some mild bruising or slight scratch during the blood sampling process. Very rarely people can have an allergic reaction to a new medication. As a precaution, people with known or suspected allergy to the medication being used will not be enrolled in the study.

Where is the study run from?
Southern Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2017 to April 2020 (updated 06/08/2019, previously: January 2020)

Who is funding the study?
Novo Nordisk (Denmark)

Who is the main contact?
Dr Clare Whicher
clare.whicher@southernhealth.nhs.uk

Contact information

Type(s)
Public

Contact name
Dr Clare Whicher

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Additional identifiers

Clinical Trials Information System (CTIS)
2017-004064-35

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
U1111-1203-0068; 37638

Study information

Scientific Title
Liraglutide and the management of overweight and obesity in people with schizophrenia: a pilot study

Acronym

Study objectives

The aim of the study is to gather feasibility data on recruitment, consent, retention, adherence and dropout rates for using liraglutide in people with severe mental illness.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/4/2019 by South Central - Hampshire B Research Ethics Committee, Level 3 Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, Tel: +44 (0)207 1048055, Email: nrescommittee.southcentral-hampshireb@nhs.net, REC ref: 18/SC/0085

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

Participants will be randomised to either once daily subcutaneous liraglutide titrated to 3 mg daily or placebo for 6 months.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Liraglutide

Primary outcome(s)

Feasibility outcome measures:

1. Time to reach recruitment target as defined by the time from first participant screened to randomisation of the 60th participant
2. Number of participants required to be screened in order to reach recruitment target as defined by the number of participants attending a screening visit
3. Participant attrition rate as defined by the number of participants not available for follow-up at the final study visit as per the research protocol
4. Adherence to the investigational medicinal product as defined by the number of empty cartridges returned at each visit by trial participants divided by the total number of cartridges prescribed. Adherence will be analysed both as a continuous variable and by the number of participants using at least 70% of prescribed trial medication over 12 weeks and 26 weeks

5. Change in weight at 12 and 26 weeks, defined as weight in kilograms (kg) at 12 and 26 weeks minus weight in kg at randomisation

Key secondary outcome(s))

Measured at baseline, 3 and 6 months:

1. Weight measured in kilograms
2. BMI calculated from weight(kg) divided by height in metres squared
3. Waist circumference measured in cm
4. Symptoms of psychosis measured using the brief psychiatric rating scale (BPRS)
5. HbA1c will be a fasting blood sample measured in mmol/mol
6. Fasting plasma glucose (FPG) will be a fasting blood sample measured in mmol/l
7. Fasting lipids will be a fasting blood sample measured in mmol/l
8. Systolic and diastolic blood pressure measured with a blood pressure machine in mmHg
9. Adherence to randomised treatment measured as those taking more than 70% of prescribed medication over 6 month period
10. Type of diabetes medication measured as per recorded on the CRF
11. Change in type or dose of diabetes medication measured as per changes in diabetes medication at baseline and 6 months
12. Type of antipsychotic medication measured as per recorded on the CRF
13. Change in type or dose of antipsychotic medication measured as per changes in antipsychotic medication at baseline and 6 months

Completion date

05/05/2020

Eligibility

Key inclusion criteria

1. Age 18-75 years old
2. Clinical diagnosis of schizophrenia or schizoaffective disorder (defined by ICD-10 codes F20 and F25) or first episode psychosis using case note review. There is no limit on the duration of illness for those with schizophrenia or schizoaffective disorder but first episode psychosis is defined as less than 3 years since presentation to the mental health team or first antipsychotic prescription
3. Treatment with an antipsychotic, with a minimum duration of 1 month prior to entry in to the trial. No restriction is placed on the class or generation of antipsychotic
4. Ability to give written informed consent
5. Ability and willingness to take liraglutide or placebo
6. Ability to speak and read English
7. Body mass index $\geq 30 \text{ kg/m}^2$ (obese), or $\geq 27 \text{ kg/m}^2$ to $< 30 \text{ kg/m}^2$ (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes), hypertension, dyslipidaemia or obstructive sleep apnoea

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Total final enrolment

47

Key exclusion criteria

1. Physical illnesses that could seriously reduce their life expectancy or ability to participate in the trial
2. A co-existing physical health problem that would, in the opinion of the principal investigator, independently impact on metabolic measures or weight, e.g. Cushing's syndrome.
3. Severe renal or hepatic impairment
4. Inflammatory bowel disease
5. Contraindications to Saxenda®: Hypersensitivity to liraglutide or to any of the excipients
6. Use of other pharmacological products for weight management
7. Mental illnesses that could seriously reduce their ability to participate in the trial, including significant suicidality. Every patient in contact with the Southern Health Trust has a risk assessment which is recorded on the electronic patient record (RIO). If the risk assessment states that they are at "High" risk of harm to themselves, we would exclude the patient from the study. In addition, prior to recruitment, we will approach any potential participant's care coordinators to verify the currently recorded risk, to ensure that the risk status has not changed.
8. Current pregnancy or a desire to become pregnant. Mothers who are less than 6 months post-partum or breastfeeding will also be excluded. Women who become pregnant during the trial will be advised to stop the study medication and will be withdrawn from the trial
9. Significant alcohol or substance misuse which, in the opinion of the principal investigator, would limit the patient's ability to participate in the trial.
10. A diagnosis or tentative diagnosis of psychotic depression or mania.
11. A primary diagnosis of learning disability.
12. Lack of capacity. Those who lose capacity any time during the study will not be eligible to continue and will be withdrawn from the study immediately with no further study procedures carried out.
13. Cognitive impairment which would impair participants ability to self-administer trial medication
14. History of type 1 diabetes

Date of first enrolment

02/07/2018

Date of final enrolment

31/10/2019

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Southern Health NHS Foundation Trust

United Kingdom

SO30 3BJ

Sponsor information

Organisation

Southern Health NHS Foundation Trust

ROR

<https://ror.org/03qesm017>

Funder(s)

Funder type

Industry

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

The datasets generated during and/or analysed during the current study are/will be available upon request from Clare Whicher (clare.whicher@southernhealth.nhs.uk) from 01/04/2020.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No