ISRCTN76893830 https://doi.org/10.1186/ISRCTN76893830

Is it safe to stop insulin injections in older adults with type 2 diabetes?

Submission date
05/12/2024

Recruitment status
No longer recruiting

Registration date
12/12/2024

Overall study status
Completed

Last Edited
20/01/2025

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
Type 2 diabetes (T2D) is a long-term health problem that causes the sugar level in the blood to become too high. It is becoming more common across the world and can cause other health problems if not treated. The best way to treat T2D is by eating a healthy diet and exercising. However, some people with T2D will need to take medicine in the form of pills or injections to manage it. Some older adults may have used injections containing insulin (a hormone that controls sugar levels in the body) for many years because their diabetes was not well controlled before. In Scotland, around 12% of people over 70 years old with T2D use insulin injections to treat their diabetes. However, insulin injections may make their blood sugar go too low, which is not good, especially for older people. Some of them even need help from others to give these injections, which makes them less independent and may affect their quality of life. T2D happens because the body cannot use insulin as well as it should and the pancreas (an organ in our body that makes insulin) is not working right over time. But the good news is that most people with T2D can still make insulin even though they have had T2D for many years. As some people get older, they eat a healthier diet or lose weight. This means insulin injections may not need to be continued even if they needed insulin when they were younger. This project aims to make treating diabetes easier for older people with T2D by stopping insulin injections for those who no longer need them.

Who can participate?
Patient participants aged 70 years old and above who require community nurse support to administer insulin, or have a clinical frailty score of 5 or above. Any general practitioners, community nurses or care home staff involved in the care of the participants and implementation of the study.

What does the study involve?
This study will use a blood test to measure a substance called C-peptide to find out how much insulin the body is making and find a safe way to stop insulin injections by replacing them with another diabetes treatment. The study will also see how this change affects their diabetes control and quality of life.

What are the possible benefits and risks of participating?
The study team spoke to people who are currently using insulin injections every day and they were happy about the project because it will give some patients more independence and freedom. They will also have fewer worries about their blood sugar going too low. They have agreed and are in favour of reducing the intake of insulin injections. Furthermore, it will also help the healthcare system because this will reduce the need for daily nurse visits, as some older patients need help with their insulin injections.

Participants may see higher blood sugar levels after stopping insulin. This is prevented by starting another type of medication used to treat type 2 diabetes. These are GLP-1 analogues (GLP-1 RA). They act like a natural hormone and make your body produce more insulin on its own which also reduces appetite. They can be given in tablet form every morning or as injections once a week.

The study will also use a continuous glucose monitoring system which allows the study team to remotely review participants' blood sugar levels for necessary actions to be taken if their sugar levels are concerning. The team will provide participants with an information leaflet about what to do when they have symptoms of high or low blood sugar. They will also be able to contact a member of the research team for advice.

These are licensed medicines to treat T2D. Several large drug trials have been carried out to study these medicines. ‘Tummy’ disturbance (nausea, vomiting, bloating, loose stool) is the most common side effect that has been reported. The symptoms are not reported as severe by older patients in the trial. They can also reduce weight which can be good or bad depending on each individual.

Where is the study run from?
Ninewells Hospital and Medical School, NHS Tayside, UK

When is the study starting and how long is it expected to run for?
July 2024 to December 2025

Who is funding the study?
1. NHS Tayside Charitable Foundation
2. Chief Scientist Office, Scottish Government Health and Social Care Directorate

Who is the main contact?
Prof Ewan Pearson, E.Z.Pearson@dundee.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Ewan Pearson

Contact details
Pearson Group, Mailbox 12
Level 5, Corridor H,
Ninewells Hospital and Medical School

Dundee
United Kingdom
DD1 9SY
+44 1382660111
E.Z.Pearson@dundee.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
328591

Central Portfolio Management System (CPMS)
58236

Protocol serial number
2-052-23

Study information

Scientific Title
Safety and feasibility of insulin simplification or cessation in frail older adults with type 2 diabetes: a pilot study of CLASP (using C-peptide to clarify, simplify and personalise type 2 diabetes management in frail older adults)

Acronym
CLASP pilot study

Study objectives
The hypothesis is that older adults with type 2 diabetes prescribed long-term insulin therapy who have C-peptide levels in keeping with retained endogenous insulin secretion will be able to stop insulin therapy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/07/2024, East of Scotland Research Ethics Service (Tayside Medical Science Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, United Kingdom; +44 1382383878; tay.eosres@nhs.scot), ref: 23/ES/0031

Primary study design
Observational

Study design
Pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Treatment of type 2 diabetes in older adults with frailty.

Interventions
This is a small observational study where individuals found to have retained endogenous insulin secretion will have their insulin therapy gradually withdrawn while substituting with GLP-1 receptor agonists (either oral semaglutide or injectable semaglutide, depending on the individual's preference). All participants will have C-peptide levels tested and those with C-peptide equal to or above 900pmol/L will be classified as having retained endogenous insulin secretion and recruited into the study. Baseline measures will include HbA1c, eGFR, clinical frailty score (using the Rockwood Clinical Frailty Scale), height, weight, skeletal muscle mass and function assessment, blood pressure, heart rate, participants reported symptoms of hypoglycaemia, and questionnaires (Diabetes Treatment Satisfaction Questionnaire, Sarcopenia and Quality of Life, Audit of Diabetes Dependent Quality of Life Senior). All assessments will be repeated at the end of the study for each participant (except for C-peptide level which will not be repeated). Participants' glucose levels will be monitored using FreeStyle Libre3 throughout. Participants who agreed to be interviewed will be interviewed during the study to assess their acceptability of the intervention.

Healthcare professionals including general practitioners, community nurses, pharmacists and care home staff will be approached for semi-structured interviews to assess for feasibility and acceptability of the insulin cessation pathway.

Intervention Type
Other

Primary outcome(s)
The percentage of patients stopping insulin measured using data collected in the study records at one timepoint

Key secondary outcome(s)
1. The following secondary outcome variables will be measured using data from medical records, case report forms and the continuous glucose monitor (CGM) device:
1.1. Hospital admissions with hyperosmotic hyperglycaemic state
1.2. Diabetes ketoacidosis or severe hypoglycaemia or ambulance call out for severe hypoglycaemia
1.3. Participant-reported hypoglycaemic episodes
1.4. The time below range on the CGM device
2. Participants' acceptability of stopping insulin, healthcare professionals or care home staff of insulin cessation pathway measured using data collected during semi-structured interviews at one timepoint

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Patient participants
1. Age 70 years old and above
2. Frailty - either care home residents, patients who require community nurse support to administer insulin, or has a clinical frailty score of 5 or above

3. Diagnosis of type 2 diabetes of more than 3 years
4. Current insulin prescription
5. HbA1c below 70mmol/mol
6. Random C-peptide level of 900pmol/L or above with paired serum glucose above 3.9mmol/L
7. BMI 25kg/m2
8. Has access to a smartphone or is willing to use one provided by the study team

Healthcare professional participants
Any general practitioners, community nurses or care home staff involved in the care of the participants and implementation of the study

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
70 Years

Upper age limit
100 Years

Sex
All

Key exclusion criteria
1. eGFR below or equal to 30ml/min/1.73m2
2. Current GLP-1 analogue prescription
3. Current oral corticosteroid prescription
4. Previous severe intolerance to GLP-1 analogue
5. Previous history of severe pancreatitis
6. History of medullary thyroid carcinoma, MEN-2 or family history of MEN-2
7. Active malignancy except basal cell or squamous cell carcinoma of the skin
8. If an individual is unable to consent

Date of first enrolment
13/12/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Tayside
Ninewells Hospital and Medical School
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
NHS Tayside Charitable Foundation

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Professor Ewan Pearson (e.z.pearson@dundee.ac.uk)

IPD sharing plan summary
Available on request