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Hybrid closed loop insulin pump system for people with diabetes caused by chronic pancreatitis

Submission date
20/04/2026

Recruitment status
Not yet recruiting

Registration date
06/05/2026

Overall study status
Ongoing

Last Edited
06/05/2026

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
People with chronic pancreatitis often develop diabetes as a result of damage to the pancreas (sometimes called type 3c or pancreatogenic diabetes). Managing blood sugar levels in this condition is particularly difficult because people may also experience pain, digestion problems and unpredictable glucose changes. Currently, treatment guidance is largely based on evidence from other types of diabetes, and there is very little research on whether newer diabetes technologies are suitable for this group.
Advanced hybrid closed-loop insulin systems combine an insulin pump with a glucose sensor to automatically adjust background insulin levels. These systems are widely used in type 1 diabetes but have not been studied in people with diabetes caused by chronic pancreatitis.
The aim of this study is to find out whether it is feasible and acceptable to run a larger clinical trial comparing advanced hybrid closed-loop insulin therapy with standard insulin treatment in people with chronic pancreatitis–related diabetes. The study will also explore participants' experiences of using these technologies and of taking part in the trial.

Who can participate?
Adults aged 18 years or older who:
• Have chronic pancreatitis and diabetes related to their pancreatic disease
• Are treated with insulin (twice-daily injections or multiple daily injections)
• Have above-target blood glucose levels or experience problematic low blood sugars
People cannot take part if, for example, they have type 1 or type 2 diabetes, have had pancreatic cancer or major pancreatic surgery, are currently using an insulin pump, are pregnant, or have other conditions that would make participation unsafe or difficult.

What does the study involve?
A total of 24 participants will take part in this single-centre study at Newcastle Diabetes Centre. After joining the study and completing baseline assessments, participants will be randomly allocated (by chance) to one of two groups:
• Advanced hybrid closed-loop group: participants will use an insulin pump that automatically adjusts insulin delivery using information from a continuous glucose monitor, alongside training

and clinical support.
• Standard care group: participants will continue their usual NHS care, which typically involves insulin injections and continuous glucose monitoring.
The study lasts around 16 weeks, including a run-in period and a 12-week study phase. Participants will attend up to 10 study visits, some face-to-face and some remotely (by phone or video). These visits will include support with diabetes management, review of glucose data, questionnaires, and routine blood tests. A smaller number of participants will also be invited to take part in an interview to share their experiences of the study.

What are the possible benefits and risks of participating?
Participants may benefit from:
• Extra support with diabetes management
• Access to advanced diabetes technology (if allocated to that group)
• Helping to inform future research and improve care for others with chronic pancreatitis and diabetes
The risks are similar to those of usual diabetes care and include low or high blood sugar levels, mild discomfort from blood tests or sensor insertions, and possible skin irritation from devices. Some questionnaire or interview questions may feel upsetting, but participants can skip questions or stop at any time. All participants will continue to have access to their usual clinical team throughout the study.

Where is the study run from?
The study is run from Newcastle Diabetes Centre, Freeman Hospital, Newcastle upon Tyne, UK, and is sponsored by Newcastle upon Tyne Hospitals NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
The study is expected to start after regulatory approvals are in place. Each participant will take part for approximately 16 weeks, and the overall study is expected to run over approximately 18–24 months, including recruitment and analysis.

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR) as part of a Doctoral Fellowship programme.

Who is the main contact?
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Contact information

Type(s)
Public, Principal investigator, Scientific

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Central Portfolio Management System (CPMS)
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National Institute for Health and Care Research (NIHR)
303033

Study information

Scientific Title
Advanced hybrid Closed Loop In people with diabetes secondary to chronic Pancreatitis (CLIP): A feasibility randomised controlled trial

Study objectives
The primary objective of this feasibility trial is to examine the feasibility of delivering a full-scale RCT within NHS services, comparing AHCL therapy with standard care (insulin pens and continuous glucose monitoring).
Feasibility criteria will be assessed against four a priori criteria defining acceptable levels of (i) Recruitment, (ii) Treatment adherence, (iii) Participant retention and (iv) data completeness.
Secondary objectives are to examine the suitability of proposed clinical and health economic measures including patient reported outcome measures. Secondary outcomes from qualitative data will aim to examine the experience of trial processes in addition to the acceptability and usability of AHCL in this population

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/04/2026, Nottingham1 REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; 02071048115; Nottingham1.rec@hra.nhs.uk), ref: 23/EM/0034

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control

Placebo

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Diabetes, chronic pancreatitis

Interventions
If participants are interested to take part, they will be invited to an initial baseline visit to complete baseline assessments and have blood samples taken. These samples will include routine blood samples and additional samples for research.
Patients will then attend a randomisation visit in which they will be allocated to either of the study arms. Feedback will be collected at this point about their thoughts with the randomised group and whether they would like to continue in the study.
The third visit will be an education visit to support participants with their current devices and any new device.
The fourth visit will be a remote review of their blood sugar profile as we would normally do in a telephone clinic appointment. We will also address any queries or problems they have with the study devices.
The fifth visit is an in-person (face to face) review. This will be similar to their usual clinic appointments where we will review their study device and insulin regime. We will also take a blood sample to check their sugar control (HbA1c) and additional research blood sample.
The sixth visit will be a further telephone review as per the fourth visit.
The seventh visit will be similar to the fifth visit however, there will be no blood sampling.
Visit 8 and 9 will be telephone reviews similar to the fourth visit.
Visit 10 will be the final visit which would be in person to repeat all the blood samples taken at baseline. Participants will be invited to complete questionnaires and if agreeable an interview.

Intervention Type
Other

Primary outcome(s)
1. Recruitment rate measured using Percentage of eligible participants who agree to take part at During recruitment period

2. Reasons for declining participation measured using descriptive recording by study team at point of recruitment

3. Completeness of baseline data collection measured using Proportion of required baseline variables collected, with documentation of missing data and reasons at Baseline (up to 4 weeks prior to randomisation)

4. Acceptability of randomisation measured using Participant agreement to randomisation and continuation in allocated arm at randomisation

5. Treatment adherence rate measured using Percentage of participants attending follow-up appointments and engaging with agreed action plans at Throughout 12 week study period

6. Participant retention rate measured using Percentage of participants completing the 12 week study phase at 12 weeks

Key secondary outcome(s))

1. HbA1c, glucose, C peptide, insulin total daily dose measured using Blood sampling and laboratory analysis at Baseline (–4 weeks; HbA1c also at week 0) and 12 weeks

2. Continuous glucose monitoring (CGM) metrics measured using Time in range (3.9–10.0 mmol /L), Time below range (<3.9 mmol/L and <3.0 mmol/L), Time above range (>10.0 mmol/L and >13. 9 mmol/L), Coefficient of variation, Standard deviation of mean glucose, Mean sensor glucose at Baseline and 12 weeks

3. Diabetes distress measured using Problem Areas in Diabetes (PAID) questionnaire at Baseline and 12 weeks

4. Hypoglycaemia awareness measured using Gold score and Hypoglycaemia Awareness Questionnaire (Hypo AQ) at Baseline and 12 weeks

5. Fear of hypoglycaemia measured using Hypoglycaemia Fear Survey II at Baseline and 12 weeks

6. Self management practices measured using Diabetes Self Management Questionnaire (DSMQ) at Baseline and 12 weeks

7. Treatment satisfaction measured using Diabetes Treatment Satisfaction Questionnaire (DTSQ) at Baseline and 12 weeks

8. Impact of automated hybrid closed loop system measured using INSPIRE questionnaire at 12 weeks (AHCL arm only)

9. Patient engagement with health measured using Consumer Health Activation Index (CHAI) at Baseline and 12 weeks

10. Anxiety and depression symptoms measured using Hospital Anxiety and Depression Scale (HADS) at Baseline and 12 weeks

11. Sleep quality measured using Pittsburgh Sleep Quality Index (PSQI) at Baseline and 12 weeks

12. Quality of life measured using EQ 5D 5L questionnaire at Baseline and 12 weeks

13. Patient reported global change measured using Patient Global Impression of Change (PGIC) at 12 weeks

14. Healthcare utilisation and treatment costs measured using Recording of GP visits, hospital attendances, dietitian and diabetes nurse contacts, equipment, medication and education costs at Throughout study period; assessed at 12 weeks

Completion date

31/05/2027

Eligibility

Key inclusion criteria
1. A confirmed diagnosis of CP and diabetes
2. Age >=18 years
3. HbA1c >=58mmol/mol or disabling hypoglycaemia (when hypoglycaemia occurs frequently or without warning, so the person is constantly anxious about having hypoglycaemic episodes) at screening as per NICE guidance
4. On insulin (twice daily or MDI)
5. Minimal daily insulin requirement of >=8 units and maximum of 250 units per day

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Known diagnosis of T1DM or T2M
2. Age ≤18 years
3. History of pancreatic cancer
4. Pregnant or planning pregnancy or breastfeeding
5. History of partial or total pancreatectomy, excluding Frey's procedure
6. Currently using an insulin pump
7. Hearing or visual impairment or impairment in dexterity that would hinder ability to manage study devices
8. Untreated coeliac disease, adrenal insufficiency or hyperthyroidism or hypothyroidism
9. Current alcohol excess or illicit drug misuse or prescription drug abuse
10. Diagnosed with an eating disorder
11. Skin conditions located at sites of sensor insertion such as psoriasis or bacterial skin infection
12. Any condition that in the assessment of the investigator would impair the ability of the participant to give informed consent

Date of first enrolment
01/06/2026

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
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Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication