

Increasing physical exercise to preserve beta cell function in adult patients with type 1 diabetes mellitus (T1DM)

Submission date

21/04/2011

Recruitment status

No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date

18/10/2011

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

14/02/2018

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

PB-PG-0609-19093

Study information

Scientific Title

Increasing physical exercise to preserve beta cell function in adult patients with type 1 diabetes mellitus (T1DM): a randomised controlled trial

Acronym

T1DM

Study objectives

Intensive exercise preserves beta cell function in patients with T1DM

On 04/10/2013, the anticipated end date was changed from 31/03/2013 to 31/12/2014.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Birmingham, East, North and Solihull Research Ethics Committee, February 2010, ref: 10/H1206/4

Primary study design

Interventional

Study design

Phase 1: Quantitative study, Phase 2: Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 1 diabetes mellitus

Interventions

Exercise will be supervised, graded and for a minimum of 150 min/week aiming for 240 min /week over a 1-year period versus control group (no exercise)

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. The proportion of patients with T1DM who started the intervention
2. The proportion who adhered to the required intensity of exercise
3. The proportion who dropped out
4. The rate of exercise uptake in the non-intervention arm, an effect which is important to incorporate into the trial design because it will dilute the effect of the intervention observed within the trial
3. The rates of loss of beta cell function (effect size) in the intervention and control arm to enable the power calculations for the definitive trial to be refined

Key secondary outcome(s)

Beta cell function-measured using a meal stimulate C peptide assay at the study onset, 6 months and 12 months time intervals.

Completion date

31/12/2014

Eligibility

Key inclusion criteria

1. A clinical diagnosis of T1DM made within the previous 3 months
2. Age 16-60 years at time of diagnosis
3. Willing to monitor and adjust insulin in order to safely undertake exercise programme

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pregnancy
2. Inability to give informed consent
3. Inability or unwilling to exercise
4. Any psychological disease likely to interfere with the conduct of the study
5. Patients on beta blocker therapy or other therapies that affect heart rate

Date of first enrolment

01/04/2011

Date of final enrolment

31/12/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Institute of Biomedical Research

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham (UK)

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit Programme

Results and Publications

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?
Results article	results	24/01/2018		Yes	No
Protocol article	protocol	18/06/2013		Yes	No