ISRCTN91388505 https://doi.org/10.1186/ISRCTN91388505

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

Submission date	Recruitment status
21/04/2011	No longer recruiting
Registration date	**Overall study status**
18/10/2011	Completed
Last Edited	**Condition category**
14/02/2018	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Parth Narendran

Contact details
Institute of Biomedical Research
University of Birmingham
Edgbaston
Birmingam
United Kingdom
B15 2TT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

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

Overall study start date
01/04/2011

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

Age group
Adult

Sex
Both

Target number of participants
92

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
England

United Kingdom

Study participating centre
Institute of Biomedical Research
Birmingam
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
University of Birmingham
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

Website
http://www.rcs.bham.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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