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The REPOSE (Relative Effectiveness of Pumps Over MDI and Structured Education) trial

Submission date
04/05/2011

Recruitment status
No longer recruiting

Registration date
11/05/2011

Overall study status
Completed

Last Edited
06/09/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
People with Type 1 diabetes (around 250,000 individuals in the UK) cannot produce insulin to control their blood glucose (sugar) and energy needs. They must inject insulin, estimating doses before eating and other activities. This may mean up to 6 injections a day, but aiming for a normal glucose level confers a high risk of hypoglycaemia (low blood glucose, which can cause coma). As a result many patients run glucose levels which are too high and go on to develop complications. Insulin can now be replaced using an infusion pump (the size of a mobile phone), which delivers insulin continuously under the skin via a small plastic tube. This approach is more expensive than multiple injections (£2500 for the pump and £1500 a year extra running costs). It may produce more stable blood glucose, less hypoglycaemia, and a more flexible lifestyle, but needs additional attention from the user. Evidence for benefit comes largely from observing people started on insulin pumps but this may overstate the benefits as those who participate are already committed to the approach or have a particular clinical need. Some of the benefit may come from the re-training and education in insulin use to allow patients to use pumps safely. Importantly, studies of high quality training alone (with standard insulin injections) show similar benefits in blood glucose control, hypoglycaemia and quality of life. No studies in adults have compared pumps with injections where the same training in insulin adjustment has been given, so the added benefit of the pumps themselves is still unclear. There is an urgent need to establish this, and identify patients who benefit the most. The aim of this study is to establish the added benefit of an insulin pump during intensive insulin therapy.

Who can participate?
Patients aged 18 and above with Type 1 diabetes

What does the study involve?
The DAFNE (Dose Adjustment for Normal Eating) course is a 1-week structured course teaching skills in insulin use, delivered in over 70 centres across the UK and Ireland (with over 10,000 individuals now trained). Patients waiting for a DAFNE course are randomly allocated to undertake either the standard DAFNE course with injections, or DAFNE incorporating use of pumps. Blood glucose control, hypoglycaemia, quality of life, acceptability, satisfaction and cost

effectiveness are compared between the two groups. We collect information for 2 years after the courses to see if differences develop after some time, or if early improvements are maintained.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
November 2011 to February 2015

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Prof. Simon Heller
s.heller@sheffield.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Simon Heller

Contact details
Department of Human Metabolism
University of Sheffield
Room EU38
Beech Hill Road
Sheffield
United Kingdom
S10 2RX
+44 (0)11 4271 3204
s.heller@sheffield.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01616784

Secondary identifying numbers
HTA 08/107/01

Study information

Scientific Title
The REPOSE (Relative Effectiveness of Pumps Over MDI and Structured Education): a multi-centre parallel group cluster randomised controlled trial

Acronym
REPOSE

Study objectives
The aim of the trial is to establish the added benefit of continuous subcutaneous insulin infusion (CSII) therapy over multiple injections on glycaemic control and hypoglycaemia in individuals with type 1 diabetes receiving similar high quality structured training in insulin therapy.

The study objectives are as follows:
1. During the randomised controlled trial (RCT) the following measures will be assessed over 2 years:
1.1. Biomedical outcomes (HbA1c, rates of hypoglycaemia, insulin dose, body weight, albumin-creatinine ratio)
1.2. Quantitative and qualitative psychosocial outcomes [quality of life (generic and diabetes specific), treatment satisfaction, fear of hypoglycaemia, hypoglycaemia unawareness, self-efficacy, social support, adherence to treatment, emotional well-being, acceptability of technology]
1.3. Adverse events (severe hypoglycaemia, hospital admissions with hypoglycaemia, diabetic ketoacidosis)
2. Through a combined analysis of the quantitative and qualitative measures we will identify factors which predict and/or help explain outcomes on CSII
3. A cost effectiveness analysis will be undertaken to determine whether the marginal benefits of CSII over optimised multiple daily injection (MDI) (if demonstrated) are commensurate with the marginal costs, as reflected in a cost per quality-adjusted life years (QALY) acceptable to National Institute for Health and Clinical Excellence (NICE)

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West, 26/04/2011, ref: 11/H1002/10

Study design
Multi-centre parallel-group cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
The intervention group will be allocated to CSII (Continuous subcutaneous insulin infusion) pump therapy and will attend a 1 week DAFNE (Dose Adjustment for Normal Eating) structured education course followed by a 2 year follow up period during which they will continue to use the CSII treatment.

The standard group will be allocated to MDI (multiple daily injection) treatment and will attend a 1 week DAFNE course followed by a 2 year follow up period during which they will continue to use MDI.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Insulin

Primary outcome measure
1. The change in HbA1c after 2 years in those participants whose baseline HbA1c was at or above 7.5% (58mmol/mol)
2. The proportion of participants reaching the NICE target of a HbA1c level of 7.5% (58mmol /mol) or less

Secondary outcome measures
Biomedical Endpoints:
1. Hypoglycaemia (severe & moderate)
2. Insulin dose
3. Body weight
4. Blood lipids & proteinuria
5. Diabetic ketoacidosis

Ancillary Study Endpoints:
The ancillary study endpoints will include a prospective psychosocial research component employing mixed methods, quantitative (questionnaires) and qualitative (interviews) approach in order to:
1. Establish whether, and why, there are differences in QoL and other psychological outcomes between patients using CSII and MDI regimens
2. Examine whether, and why, QoL and other outcomes change over time
3. Understand and explore the added benefit (if any) of CSII technology over MDIs from patients

and educators perspectives
4. Look at why some patients may do better than others using CSII
5. Explore acceptability of, and reasons for, discontinuing (pump) treatment
6. Enhance understanding, and assist in the interpretation, of trial outcomes (e.g differences in HbA1c between the two arms)

Quantitative data will be collected at baseline, 6 months, 1 year and 2 years. Data collected will be Quality of life measures DSQOOL, WHOQOLBREF, SF12 and EQ5D; the Hypoglyceamia Fear Scale (HFS); Diabetes Treatment Satisfaction Questionnaire (DTSQ) and Hospital Anxiety and Depression Scale (HADS).

Qualitative data will involve a representative sub-sample of around 40 participants, to include 20 from the CSII arm and 20 from the MDI arm of the trial. These patients will be interviewed within 2 weeks of completion of their courses and around 6 months later. Patients educators will also be invited to take part in an interview and these interviews will also take place within about 2 weeks of the course completion.

Health Economic
1. Incremental cost-effectiveness ratio
2. Sensitivity analyses

Demographic Measures: Demographics collected will include sex, age, ethnicity, religion and socioeconomic status.

Overall study start date
01/11/2011

Completion date
28/02/2015

Eligibility

Key inclusion criteria
1. Aged 18 years and above
2. Have had type 1 diabetes for at least 12 months (as assessed by date clinically diagnosed)
3. Is fluent in speaking, reading and understanding English
4. Has no preference to either CSII or MDI arm of the study and is happy to be randomised
5. Is currently using or willing to switch to insulin detemir
6. Is willing to undertake self monitoring of blood glucose (SMBG), carbohydrate counting and insulin self adjustment (enrolment staff should check that any participant with a baseline HbA1c of above 12% is willing to complete SMBG)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
280

Key exclusion criteria
1. Inability to give informed consent
2. Is pregnant or planning to become pregnant within the next 2 years
3. Has used CSII within the last 3 years
4. Has already completed a diabetes education course
5. Has severe needle phobia
6. Has a current history of alcohol or drug abuse
7. Has a history of heart disease within the past 3 months
8. Has hypertension that is not under control with hypertensive medication (diastolic blood pressure > 100mmHg and or sustained systolic level > 160)
9. Has renal impairment with a chance of needing renal replacement therapy within the next 2 years (enrolment staff should check that creatinine levels are not above 200 µmol/L)
10. Has recurrent episodes of skin infections
11. Has serious or unstable medical or psychological conditions
12. Has taken part in any other investigational clinical trial during the 4 months prior to screening
13. Has any other issue that may preclude the participant from satisfactory participation in the study based on investigatory judgement

Date of first enrolment
01/11/2011

Date of final enrolment
28/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S10 2RX

Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Foundation Trust (UK)

Sponsor details
Brenda Zinobar
Research Department
STH NHS Foundation Trust
11 Broomfield Road
Sheffield
England
United Kingdom
S10 2SE
+44 (0)11 4226 5944
brenda.zinober@sth.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.sth.nhs.uk/

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/03/2017

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	03/09/2014		Yes	No
Results article	results	07/02/2017		Yes	No
Results article	results	30/03/2017		Yes	No
Results article	results	01/04/2017		Yes	No
HRA research summary			28/06/2023	No	No