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

Submission date 04/05/2011	Recruitment status No longer recruiting	[X] Prospectively registered	
		[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
11/05/2011	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
06/09/2019	Nutritional, Metabolic, Endocrine		

## 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

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# Additional identifiers

ClinicalTrials.gov (NCT) NCT01616784

Protocol serial number HTA 08/107/01

# Study information

Scientific Title

The REPOSE (Relative Effectiveness of Pumps Over MDI and Structured Education): a multicentre 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

# Study type(s)

Treatment

# 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(s)

- 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

#### Key secondary outcome(s))

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.

#### 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

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

#### Sex

All

#### 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

United Kingdom

England

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

# Sponsor information

#### Organisation

Sheffield Teaching Hospitals NHS Foundation Trust (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, Health Technology Assessment (HTA), HTA

# **Funding Body Type**

Government organisation

# Funding Body Subtype

National government

#### Location

**United Kingdom** 

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

# **Study outputs**

Output type	Details	Date created Date	e added Peer reviewed	? Patient-facing?
Results article	results	07/02/2017	Yes	No
Results article	results	30/03/2017	Yes	No
Results article	results	01/04/2017	Yes	No
Protocol article	protocol	03/09/2014	Yes	No
HRA research summary		28/0	06/2023 No	No
Participant information sheet	Participant information sheet	11/11/2025 11/1	11/2025 No	Yes