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Oxidative stress markers and insulin pump therapy

Submission date	Recruitment status	[ ] Prospectively registered
24/06/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/09/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/12/2016	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Generation of harmful free radicals – oxidative stress - in the wake of poor glucose control is a key link between diabetes and many of the cardiovascular (heart and circulation) conditions that cause much of the health issues that occur in this patient group. In particular, oxidative stress is a critical player in large vessel disease that leads to myocardial infarction (heart attack), stroke and peripheral vascular disease (a condition where fatty deposits have built up in blood vessels and restricts the blood supply) on account of damage to the protective lining of arteries. Oxidative stress also alters molecules that carry fats in the blood and is associated with increased stickiness between platelets and white blood cells. Research has demonstrated that insulin pump therapy in people with type 2 diabetes is associated with reduced markers of oxidative stress as well as less excursion (i.e. rapid change) in blood glucose levels, however, in the UK pump therapy is reserved for people with type 1 diabetes and oxidative stress markers have not been explored in this group. Moreover, newer techniques are available to measure oxidative stress and platelet-white cell adhesion has not been examined in any group of people on pump therapy. We aim to compare markers of oxidative stress and platelet-white cell adhesion in people with type 1 diabetes using insulin pump therapy compared with those on multiple daily insulin injections. As the previous research suggested that oxidative stress was lower in people using statin therapy to reduce cholesterol the groups will be further equally subdivided into those receiving statin therapy compared with those who are not.

Who can participate?
Adults aged 18-60 with type 1 diabetes that have their condition managed either by insulin pump therapy (CSII) or multiple daily insulin injections.

What does the study involve?
Participants attend go to the study clinic on one occasion to provide a fasting sample urine sample (to check oxidative stress markers) and also blood sample to measure platelet-white cell adhesion and lipid levels along with measurement of diabetes control. Height, weight and blood pressure for each participant is also recorded.

What are the possible benefits and risks of participating?
No direct patient benefits and no risks as only providing a urine and blood sample on one occasion.

Where is the study run from?
Highland Diabetes Institute, University of the Highlands and Islands (UK)

When is the study starting and how long is it expected to run for?
November 2014 to December 2015

Who is funding the study?
NHS Highland Research & Development Endowment Fund (UK)

Who is the main contact?
Professor Sandra MacRury

Contact information

Type(s)
Public

Contact name
Prof Sandra MacRury

ORCID ID
http://orcid.org/0000-0001-7599-1302

Contact details
Division of Health Research
University of the Highlands and Islands
Centre for Health Science
Inverness
United Kingdom
IV2 3JH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
602SM

Study information

Scientific Title

A pilot study to investigate whether patients with type 1 diabetes receiving insulin pump therapy have reduced markers of oxidative stress and cardiovascular risk compared to those on multiple daily injections

Study objectives
We postulate that patients with type 1 diabetes managed by insulin pump therapy (CSII) and receiving statin therapy will have lower levels of oxidative stress, endothelial dysfunction and platelet-monocyte conjugation than those on CSII not on statin therapy or those on MDI insulin therapy with or without statin therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee, 25/04/2014, ref: 14/NS/0054

Study design
Single-centre pilot comparative clinical study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
The study population will be drawn from the diabetes population attending the diabetes clinic at Raigmore Hospital in Inverness. Forty eight people with type 1 diabetes > 5 years will be recruited. 50% of these participants (12 on pump therapy and 12 not on pump therapy) should be receiving statin therapy for a minimum of 6 months duration.

Patients will attend for a single visit having fasted from 10 pm the previous evening and at which a venous blood sample will be drawn. Patients will provide a urine sample from the first void on the visit day. Height, weight and blood pressure will be assessed at the visit

Intervention Type
Mixed

Primary outcome measure
To determine if insulin pump therapy reduces oxidative stress, endothelial dysfunction and platelet-monocyte conjugation in patients with type 1 diabetes

Secondary outcome measures
To determine if insulin pump therapy + statins have a synergistic effect in terms of reducing oxidative stress, endothelial dysfunction and platelet-monocyte conjugation in patients with type 1 diabetes

Overall study start date
01/11/2014

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Patients with type 1 diabetes
2. Group A: patients not on insulin pump therapy and not on statin n=12
3. Group B: patients not on insulin pump therapy, but on statin n=12
4. Group C: patients on insulin pump therapy > 6 months and not on a statin n=12
5. Group D: patients on insulin pump therapy > 6 months and on a statin n=12

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Type 2 diabetes
2. Very poor glucose control (HbA1c > 84 mmol/mol (10%)
3. Renal impairment (eGFR < 60ml/min/kg)
4. Recently diagnosed patients (<5 years)
5. Smokers or recently stopped (<6 months) ex-smokers
6. Chronic inflammatory disease (e.g. rheumatoid arthritis, Inflammatory bowel disease, asthma, chronic obstructive pulmonary disease)

Date of first enrolment
01/11/2014

Date of final enrolment

31/12/2015

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Highland Diabetes Institute, University of the Highlands and Islands
Inverness
United Kingdom
IV2 3JH

Sponsor information

Organisation
University of the Highlands and Islands (UK)

Sponsor details
Executive Office
Ness Walk
Inverness
Scotland
United Kingdom
IV3 5SQ

Sponsor type
University/education

ROR
https://ror.org/02s08xt61

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Highland Research & Development Endowment Fund

Funder Name
Scottish Society of Physicians

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration