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Prevention of recurrent severe hypoglycaemia: optimised multiple daily insulin injection (MDI) versus continuous subcutaneous insulin infusion (CSII) with or without adjunctive real-time continuous glucose monitoring

Submission date
06/08/2009

Recruitment status
No longer recruiting

Registration date
18/09/2009

Overall study status
Completed

Last Edited
30/03/2023

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 often miss early warnings of falling blood glucose level. This is a major concern as it can cause the individual to collapse without warning (severe hypoglycaemia). This problem can be reversed by preventing glucose levels falling too low, but this can be difficult as high glucose levels can also be damaging. Severe hypoglycaemia can be prevented in most people while improving overall glucose control using modern insulin injections or an insulin pump. In this study, we plan to further test these treatments with a new glucose sensor which can detect low glucose levels. The aim of the study is to find the best way of managing and supporting all patients with hypoglycaemia in the future.

Who can participate?
Male or female participants aged between 18 and 74 years, who have type 1 diabetes mellitus and have experienced impaired hypoglycaemia awareness and have experienced an episode of severe hypoglycaemia.

What does the study involve?
The study will compare insulin pumps and multiple daily injections with or without continuous glucose monitoring. Participants are randomly allocated to receiving either multiple daily insulin injections or insulin pump therapy, with or without continuous glucose monitoring.

What are the possible benefits and risks of participating?
The education programme given is hoped to improve the participants' overall diabetes control for many years after the end of the study. Participants with impaired awareness of hypoglycaemia may be at risk of severe hypoglycaemia. However, all the study treatments are tailored towards strict hypoglycaemia avoidance. For participants receiving insulin pump therapy may be at risk of diabetic ketoacidosis if the insulin pump is not used correctly.

Where is the study run from?
Newcastle Upon Tyne Hospitals NHS Foundation Trust

When is the study starting and how long is it expected to run for?
The study began recruiting participants in 2010, and recruitment ended in June 2011. The study will be completed in August 2013.

Who is funding the study?
Diabetes UK

Who is the main contact?
Professor James Shaw
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Contact information

Type(s)
Scientific

Contact name
Prof James Shaw

Contact details
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Additional identifiers

EudraCT/CTIS number
2009-015396-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5052

Study information

Scientific Title

A definitive randomised controlled trial (RCT) comparing optimised multiple daily insulin injection (MDI) and continuous subcutaneous insulin infusion (CSII) with or without adjunctive real-time continuous glucose monitoring for the prevention of recurrent severe hypoglycaemia

Acronym
hypo COMPASS

Study objectives
This study asks whether, in people who have diabetes mellitus and suffer from impaired or altered awareness of low blood sugars (hypoglycaemia), it is possible to restore that awareness and therefore prevent severe hypoglycaemia by rigorously preventing the participants from having any episodes of hypoglycaemia without jeopardising their overall diabetes control and using existing technology. The study will be able to answer this by analysis of a validated quantitative questionnaire that will be used throughout the study.

Please note that as of 25/10/2012, the anticipated end date for this study was updated from 31 /07/2012 to 31/08/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sunderland Research Ethics Committee,18/12/2009, ref: 09/H0904/63

Study design
Interventional multicentre randomised controlled trial, 2 x 2 factorial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
All participants will participate in an educational programme which has been validated in our single centre pilot study. This includes carbohydrate counting, discussion on glycaemic indices of food, the effect of exercise on blood glucose, the importance of detection and prevention of nocturnal hypoglycaemia and recommendations on carbohydrate administration for blood

glucose less then 4 mmol/l. Thereafter participants will be randomised to one of four intervention groups for the 24 week intervention period. The four groups are as follows:
1. Multiple daily subcutaneous insulin analogue injections (MDI). Insulins used will be insulin glargine and insulin aspart.
2. MDI using aspart and glargine with real time continuous glucose monitoring
3. Continuous subcutaneous insulin infusion (CSII) using insulin aspart
4. CSII using insulin aspart with real time continuous glucose monitoring

Participants will be followed up monthly during the 24 week intervention period after which they will be followed up at 6, 12 and 18 months. All diabetes care after the 24 week intervention period will return to routine NHS care.

Contact details for Patient Information Sheet:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Restoration of hypoglycaemia awareness as determined by quantitative questionnaire analysis.

Secondary outcome measures
1. Difference in rates of mild symptomatic hypoglycaemia as measured by home blood glucose diaries at 6 months and intermediate study visits
2. Difference in duration of biochemical hypoglycaemia determined by 7-day continuous glucose monitoring system (CGMS) at 6 months and intermediate study visits
3. Difference in HbA1c at 6 months and intermediate study visits
4. Difference in rates weekly 8-point glucose profiles

Overall study start date
01/12/2009

Completion date
31/08/2013

Eligibility

Key inclusion criteria
1. Male or female patients aged 18 - 74 years
2. Established type 1 diabetes mellitus (C peptide negative)

3. Experienced impaired hypoglycaemia awareness and, or at least one episode of severe hypoglycaemia as defined as by the American Diabetes Association in the previous 12 months
4. Willing to undergo intensive insulin therapy including the use of CSII (insulin pump)
5. Willing to monitor home blood glucose levels at least four times daily
6. Willing to monitor and record signs and symptoms of hypoglycaemia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 patients

Key exclusion criteria
1. Not willing to consider insulin pump therapy
2. Unable to use the technology such as real time glucose monitoring

Date of first enrolment
01/01/2010

Date of final enrolment
01/06/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Cellular Medicine
Newcastle upon Tyne
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NE2 4HH

Sponsor information

Organisation
Newcastle Upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK (UK) (ref: 07/0003556)

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	13/12/2012		Yes	No
Results article	results	01/12/2013		Yes	No
Results article	results	01/08/2018		Yes	No
Results article	results	20/12/2022	30/03/2023	Yes	No
HRA research summary			28/06/2023	No	No