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The Ambulance-Hypo Study

Submission date
05/01/2016

Recruitment status
No longer recruiting

Registration date
10/02/2016

Overall study status
Completed

Last Edited
11/08/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Hypoglycaemia is a condition usually experienced by people with diabetes when the level of sugar in the blood falls to a very low level. Hypoglycaemia is often caused by the medication people with diabetes take but it can also be caused by exercise, diet and having other conditions as well as diabetes. Hypoglycaemia causes symptoms such as tiredness and dizziness but can also cause very serious symptoms such as loss of consciousness and can even be fatal if it is not treated. In some parts of the UK, ambulance staff who attend patients with hypoglycaemia can refer them to a new care pathway aimed at preventing further episodes of hypoglycaemia. As part of this care pathway, ambulance staff give the patient's details to a nurse who is specially trained in helping people with diabetes. This nurse then contacts the patient by phone to talk about why the person had hypoglycaemia and how they can avoid it in the future. If necessary, the nurse may arrange an out-patient appointment or request that the patients' medication is changed. There have been small studies of this care pathway to see whether it is effective at preventing further episodes of hypoglycaemia. Although the results have been promising we need to collect more data to see if the care pathway can be set up in new areas and prevent future episodes of hypoglycaemia and improve overall outcomes for patients.

Who can participate?
Patients aged 18 or older living in Northamptonshire or Lincolnshire, assessed by a paramedic as hypoglycaemic.

What does the study involve?
Ambulance staff either refer patients to the new care pathway or send the patient's details to their GP. This is determined randomly. Patients allocated to the new care pathway receive help and advice from a diabetes specialist nurse who may discuss the cause of the hypoglycaemia and how it can be prevented in the future, in addition to an advice leaflet. The nurse also conducts a review of the patients' current medications to establish if any changes are required to help prevent future episodes. The other patients still receive an advice leaflet but are asked to visit their GP to discuss their hypoglycaemia. Referred patients are followed-up four weeks later. This involves sending them an invitation letter and information leaflet along with a consent form and a questionnaire to complete. Patients who consent to take part are followed up 12 months later. This involves contacting the patient's general practice to obtain relevant information about the patient, which is agreed to when the patient consents to join the study.

What are the possible benefits and risks of participating?
Participants in both groups will receive help and advice about hypoglycaemia. As the intervention does not include changes to the way in which patients with hypoglycaemia are treated there are no anticipated risks from the intervention per se. However, if participants consent to the study their GP will be made aware that they have been treated by a paramedic for a hypoglycaemic event. This may have implications for their ability to drive as the DVLA would normally be informed of the episode of hypoglycaemia.

Where is the study run from?
The study is taking place in Northamptonshire, where the ambulance service and the diabetes care service are both involved.

When is the study starting and how long is it expected to run for?
January 2015 to April 2018.

Who is funding the study?
National Institute for Health Research Collaborations for Leadership in Applied Health Research and Care East Midlands (UK).

Who is the main contact?
Dr Andy Willis

Contact information

Type(s)
Scientific

Contact name
Dr Andy Willis

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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UNOLE 0550

Study information

Scientific Title
Innovative hypoglycaemia pathway for self-care at home and admission avoidance: a partnership approach with a regional ambulance trust

Acronym
Ambulance-Hypo

Study objectives
Patients randomised to the intervention arm of the study (intervention from a diabetes nurse) will have a higher rate of evidence of discussion of the hypo and/or change in medication documented in the participants' medical notes when compared to participants randomised to the control arm (GP referral).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Nottingham 1 committee, 19/01/2016, REC ref: 15/EM/0538

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Prevention of hypoglycaemia in people with diabetes

Interventions
Patients are randomised to the intervention arm (intervention from a diabetes nurse) or the control arm (GP referral).

The intervention involves ambulance staff from East Midlands Ambulance Service attending the call-out and Diabetes Specialist Nurses working for the Integrated Care Diabetes Service in Leicester. The ambulance staff gives the patient a “Hypos can Strike Twice” information booklet.

The booklet includes information on what a 'hypo' is, their prevention and treatment as well as advice on driving. The booklet explains that the patient will be contacted by phone within two working days, by a DSN who will discuss the episode of hypoglycaemia, offer advice and suggest treatment changes (if required) in an attempt to prevent future hypoglycaemic episodes. If the DSN is unable to contact the patient by telephone a letter is sent offering them a face-to-face appointment. The general practitioner (GP) is informed following all telephone calls and consultations or if the patient refuses an appointment.

Intervention Type
Other

Primary outcome measure
Documented evidence in the patient's notes (practice notes or those maintained by DSNs) that the hypoglycaemic episode was discussed (within 4 weeks of the call-out) during a telephone consultation or a face-to-face consultation with a Health Care Professional (HCP), and that advice was given and/or changes made to their medication

Secondary outcome measures
1. Patient's satisfaction with the treatment they have received (Diabetes Treatment Satisfaction Questionnaire (Bradley, 1994)) 4 weeks after consent
2. Patient's knowledge of DVLA driving regulations relating to hypoglycaemia (unvalidated questionnaire) 4 weeks after consent
3. Patient's fear of hypoglycaemia, Fear of Hypoglycaemia Scale (Cox et al., 1987) 4 weeks after consent
4. Patient's quality of life EQ5D (The EuroQol Group, 1990) 4 weeks after consent
5. Rates of CVD and CVD-related mortality (rates of all-cause mortality) extracted from patients medical notes at 12 months after consent
6. Rate of hypoglycaemic episodes requiring repeat ambulance attendance (recorded by ambulance service) collected at 12 months after consent
7. Rate of hypoglycaemic episodes requiring repeat ambulance attendance and conveyance to hospital (including information on whether or not admitted) (recorded by ambulance service) collected at 12 months after consent

Overall study start date
01/01/2015

Completion date
20/06/2019

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent
2. Age 18 years and older
3. Able to speak and read English
4. Paramedic assessment of a hypoglycaemic event on the basis of blood glucose reading of <4.0 mmol/l
5. Lives in Northamptonshire or Lincolnshire
6. Responsible for their own care and/or medication

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
216

Total final enrolment
81

Key exclusion criteria
1. Unwilling or not able to give informed consent
2. Aged under 18 years
3. Not able to speak and read English
4. Lives outside Northamptonshire and Lincolnshire
5. Not responsible for their own care and/or their medication
6. Previously referred to the present study
7. Admitted to hospital for more than 2 days
8. Registered with a GP outside of the Northamptonshire or Lincolnshire CCGs (i.e., Nene and Corby, West Lincolnshire, East Lincolnshire, South West Lincolnshire and South Lincolnshire, respectively)

Date of first enrolment
01/03/2016

Date of final enrolment
20/06/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Diabetes Centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
East Midlands Ambulance Service NHS Trust
East Division HQ
Cross O'Cliff Court
Bracebridge Heath
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United Kingdom
LN4 2HL

Sponsor information

Organisation
University of Leicester (UK)

Sponsor details
Academic Department
Leicester General Hospital
Gwendolen Road
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LE54PW

Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Collaborations for Leadership in Applied Health Research and Care East Midlands (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
30/05/2021

Individual participant data (IPD) sharing plan
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IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2022	11/08/2022	Yes	No
HRA research summary			28/06/2023	No	No