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Effect of Flooding on the Glycaemic Control of Patients with Diabetes Mellitus

Submission date	Recruitment status
18/03/2010	No longer recruiting
Registration date	**Overall study status**
25/03/2010	Completed
Last Edited	**Condition category**
01/08/2011	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title

A Longitudinal Study on the Effect of Flooding on the Glycaemic Control of Patients with Diabetes Mellitus

Study objectives
A natural disaster such floods has a detrimental effect on glycaemic control in patients with diabetes mellitus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull and East Riding Local Research Ethics Committee approved (LRED: 08/H1304/83)

Study design
Longitudinal study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes Mellitus (type I and II)

Interventions
Data were collected using anonymous numbers assigned to each recipient and then scanned the data using a computer software called FORMIC

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
We intend to determine if glycaemic control (as assessed by HbA1c) was different amongst patients with diabetes who were flooded compared to those who were not. The analysis, to be performed by a statistician will most likely use an unpaired t test analysis following logarithmic transformation of the HbA1c data.

Secondary outcome measures

To establish if the frequency of HbA1c monitoring was different amongst those flooded compared to those who were not over the 15 months following the flooding.

Overall study start date
20/12/2008

Completion date
30/03/2009

Eligibility

Key inclusion criteria
1. All patients registered as having diabetes mellitus via pathology database
2. Age ≥ 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15,000

Key exclusion criteria
1. Nursing home patients
2. Prisoners
3. Patients dependent on professional care for management of their diabetes.

Date of first enrolment
20/12/2008

Date of final enrolment
30/03/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
220-236 Anlaby Road
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull & East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
c/o James Illingsworth
R&D Department
Office 6
2nd Floor Daisy Building,
Castle Hill Hospital
Castle Road
Cottingham
England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK (UK) (ref: 08/0003768)

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

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2011		Yes	No