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

Submission date	Recruitment status No longer recruiting	Prospectively registered	
18/03/2010		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
25/03/2010	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
01/08/2011	Nutritional, Metabolic, Endocrine		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Eric Kilpatrick

Contact details

220-236 Anlaby Road Hull United Kingdom HU3 2RW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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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