

The failing diabetic patient: Who When and Why? Meeting the needs of the poorly controlled Type 2 diabetic patient in general practice

Submission date

23/01/2004

Recruitment status

No longer recruiting

Registration date

23/01/2004

Overall study status

Completed

Last Edited

15/08/2011

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

1. To describe the characteristics of Type 2 diabetic patients with poor glycaemic control on oral therapy and ascertain any factors influencing referral for insulin therapy.
2. To ascertain patient and general practitioner beliefs and attitudes, fears and perceptions towards initiating insulin therapy in diabetic patients poorly controlled on oral treatment.
3. To develop a care package, incorporating these views, for the management of diabetic patients with poor control on oral therapy.
4. To evaluate the effect of a care package for general practice management of diabetic patients with poor control on oral treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Nutritional, metabolic and endocrine diseases: Diabetes

Interventions

Care package vs standard treatment

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1.1 Characteristics of patients (age, sex, BMI, duration of diabetes, co-morbidity and other clinical features).

1.2 Description of therapy, type and duration.

1.3 Level of diabetic control (HbA1c), duration of oral treatment failure and time to initiation of insulin treatment.

2.1 Ascertainment of factors influencing general practice management and/or hospital referral of diabetic patients with failure of oral treatment.

2.2 Ascertainment of patient and general practitioner attitudes, beliefs, fears and perceptions towards failure of oral treatment and potential insulin therapy.

3. A simple care package for general practice management of the diabetic patient failing on oral treatment.

4.1 Level of glycaemic control before and after the intervention (glycosylated haemoglobin, HbA1c).

4.2 Quality of life assessment before and after the intervention.

4.3 Alteration in use of insulin treatment following introduction of the management package.

Secondary outcome measures

Not provided at time of registration

Overall study start date

10/01/1999

Completion date

10/01/2002

Eligibility

Key inclusion criteria

Type II diabetic patients

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

10/01/1999

Date of final enrolment

10/01/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Netherlaw

Darlington

United Kingdom

DL3 7SQ

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

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Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

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	01/05/2006		Yes	No