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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
[X] 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

Protocol serial number
RRCC701F R340152

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s)
Not provided at time of registration

Completion date
10/01/2002

Eligibility

Key inclusion criteria
Type II diabetic patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre

Netherlaw
Darlington
United Kingdom
DL3 7SQ

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

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