

Family physician and endocrinologist coordination as the basis for diabetes care in clinical practice

Submission date

19/10/2007

Recruitment status

No longer recruiting

Registration date

04/12/2007

Overall study status

Completed

Last Edited

31/12/2020

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

Protocol serial number

N/A

Study information

Scientific Title

Family physician and endocrinologist coordination as the basis for diabetes care in clinical practice

Study objectives

To estimate the proportion of Diabetic Patients (DPTs) with peripheral vascular disease treated at a primary health care site after an endocrinologist-based intervention, who meet the Adult Treatment Panel III (ATP III) targets of metabolic control, as well as to compare the outcome with the results of the patients treated by endocrinologists.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was conducted in accordance with the Declaration of Helsinki and approved by the St Carlos University Hospital ethic committee in January 2003.

Study design

Single centre, prospective over 60-months period, interventional and randomised controlled study

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Diabetic patients with a peripheral vascular disease

Interventions

After a treatment period of 3 months in the Diabetes Unit of the St Carlos Hospital, 63 of the 126 patients were randomly assigned to receive treatment by the family physicians at primary care level and other 63 to receive treatment by the diabetes team at the Endocrinology Service, St Carlos Hospital for 60 months. The patients were periodically followed, at least every 2 to 4 weeks during the early stage of the trial and after each pharmacologic treatment change, and every 6 months until the completion of the follow-up period to measure the following:

1. Body weight (barefoot, with indoor clothes).
2. Waist circumference.
3. Blood pressure with appropriately sized armlet after 3 minutes in a supine position
4. Urine and blood tests. The patients collected three consecutive first-morning urine samples for the analysis of Albumin-Creatinine Ratio (ACR) and attended the laboratory at 8.30 am after 10 h of fasting to obtain a blood sample in order to determine HbA1c (Diabetes Control and Complications Trial [DCCT] standardized), total cholesterol, High Density Lipoproteins (HDL) cholesterol, triglycerides, apolipoprotein A1, apolipoprotein B and lipoprotein (a) levels.
5. Nutritional intervention based on Diabetes Nutrition and Complications Trial (DNCT): PolyUnsaturated Fatty Acids (PUFAs)/Saturated Fatty Acids (SFAs) >0.4 and MonoUnsaturated Fatty Acids (MUFAs)/SFAs >1.4.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

To estimate the proportion of participants who meet the ATP III and Steno-2 targets of metabolic control, and to compare the difference in trial outcome between the two groups. This will be assessed using the measurements described in the "Interventions" field above.

Key secondary outcome(s)

1. Progression of peripheral vascular disease at 60 months
2. New onset of micro and macrovascular complications associated with poorly controlled diabetes at 60 months
3. Morbidity and mortality at 60 months

Completion date

01/01/2008

Eligibility**Key inclusion criteria**

Diabetic patients recruited for the foot-care screening programme were tested for peripheral vascular disease and considered eligible when diagnosed. The patients were considered to have a peripheral vascular disease when they had at least one of the following:

1. Patients who underwent a peripheral vascular revascularization at least 6 months ago
2. Patients with previous non-neuropathy foot lesions at least 6 months ago
3. At least one Ankle/Brachial Index (ABI) <0.8

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

126

Key exclusion criteria

1. Diabetic patients without peripheral vascular disease
2. Younger than 18 years old or older than 85 years old

Date of first enrolment

01/01/2003

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Spain

Study participating centre

c/o Prof Martin Lagos s/n

Madrid

Spain

28040

Sponsor information

Organisation

St Carlos Hospital (Hospital Clínico San Carlos), Department of Endocrinology and Nutrition (Spain)

ROR

<https://ror.org/04d0ybj29>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St Carlos Hospital (Hospital Clinico San Carlos) (Spain)

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	31/07/2008	31/12/2020	Yes	No