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

Submission date	Recruitment status	[ ] Prospectively registered
19/10/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/12/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/12/2020	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Alfonso Calle Pascual

Contact details
c/o Prof Martin Lagos s/n
Madrid
Spain
28040
+34 913303281
acalle.hcsc@salud.madrid.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
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.

Secondary outcome measures
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

Overall study start date
01/01/2003

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

Age group
Adult

Sex
Both

Target number of participants
126

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)

Sponsor details
c/o Prof Martin Lagos s/n
Madrid
Spain
28040
+34 913303281
pmarroj@hotmail.com

Sponsor type
Hospital/treatment centre

Website

http://www.hcsc.es/

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

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