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Strategies for the introduction and implementation of a guideline for the treatment by family physicians of diabetics in the Lazio region of Italy

Submission date
05/03/2004

Recruitment status
No longer recruiting

Registration date
21/04/2004

Overall study status
Completed

Last Edited
07/02/2008

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] 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

Contact name
Dr Amina Pasquarella

Contact details
Via di Santa Costanza 53
Rome
Italy
00198

Additional identifiers

Study information

Scientific Title

Acronym
IMPLEMEG

Study objectives
The primary objective of the study is to assess the effectiveness of different strategies for the implementation of an evidence-based guideline for the management of non-complicated type 2 diabetes mellitus (DM) among GPs of the Lazio region.

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)
Treatment

Health condition(s) or problem(s) studied
Type 2 non-complicated diabetes

Interventions
Different strategies for the implementation of a guideline of non-complicated type 2 diabetes mellitus in the region of Lazio (Italy).
Eighty four GPs in each arm were randomised in the care of type 2 diabetes mellitus to:
Arm 1. Undergo a training module and administration of the guideline.
Arm 2. Receive the guideline without training.
Arm 3. Continue current practice.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The proportion of patients who were prescribed three measurements of glycosylated haemoglobin with at least two months interval per year.

Key secondary outcome(s)
1. Process of care variables on metabolic control and prevention of micro-macrovascular complications (ie proportion of overweight/obese diabetics who were prescribed methformin in monotherapy as first-choice therapy)
2. Proportion of diabetics with a complete lipid assessment per year
3. Proportion of diabetics with an eye examination or a fundus per year)

Completion date
31/12/2004

Eligibility

Key inclusion criteria
252 General Practitioners (GPs) taking part in an electronically-linked diseases surveillance network.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. Patients aged less than 40
2. Patients with complications
3. Diabetic pregnancy

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
Italy

Study participating centre
Via di Santa Costanza 53
Rome
Italy
00198

Sponsor information

Organisation
Agency for Public Health, Lazio Region, Italy (Agenzia di Sanità Pubblica della Regione Lazio)

Funder(s)

Funder type
Government

Funder Name
Ministry of Health Lazio Region (Italy)

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	04/06/2007		Yes	No
Protocol article	Protocol	14/06/2004		Yes	No