

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	<input type="checkbox"/> Prospectively registered
Registration date 21/04/2004	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 07/02/2008	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Italy

00198

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/01/2004

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

Age group

Adult

Sex

Not Specified

Target number of participants

252 GPs

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)

Sponsor details

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Sponsor type

Government

Funder(s)

Funder type

Government

Funder Name

Ministry of Health Lazio Region (Italy)

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