

Rapid improvement cycles for the therapeutic treatment of diabetes complications

Submission date 16/01/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/04/2009	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Danilo Orlandini

Contact details
Via Amendola 2
Reggio Emilia
Italy
42100
+39 0522 335 440
danilo.orlandini@ausl.re.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Can rapid improvement cycles improve the therapeutic treatment of diabetes complications? A pragmatic cluster randomised controlled trial.

Study objectives

The scope of this study is to assess whether the application of rapid improvement cycles involving specific and circumspect clinical topics of the organisation of Italian Diabetic Units (prevention of arteriosclerotic cardio-vasculopathies; prescription of anti-hypertension drugs; prescription of anti-aggregant drugs) is able to improve the processes and the outcomes of care to diabetics. The Diabetic Units in the action branch will participate in the training course on rapid improvement cycles, then will produce quality improvement projects and will receive support and coaching from an expert.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Interventional pragmatic cluster randomised, controlled clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Diabetes complications

Interventions

The selected Diabetes Units will attend the 'basic course' that discusses the topic of the correct method for inputting data for the indicators that will be assessed in this study, and the method by which aptitude to input data will be verified.

The Diabetic Units in the control branch will not receive any further education or support in addition to that obtained from participating in the basic course.

The Diabetic Units that will belong to the action branch will participate in the training course on rapid improvement cycles. The topic of the theoretical-practical course will be improvement of

the quality of medical care; participants will learn skills in using the improvement methods of the Intermountain Healthcare's Mini-advanced Training Program In Health Care Delivery Improvement designed to facilitate the development of the necessary skills for participating dynamically in quality improvement activities. In the three following months, participants will produce a quality improvement project on the first topic discussed in the study and, at the same time, will receive support and coaching from an expert in quality improvement methodologies, through planned tele-conferences and remote assistance (e-mails). At the end of this three-month period, the action branch participants will present their projects in a session during which they will be reviewed and assessed by a group of experts in improving the quality of medical care.

During the following period, the participants will carry out improvement projects on the other topics discussed in the study, and a year after the study started, the improvement ventures will be presented in an interim meeting lasting one day, to which the Diabetic Units enrolled in the action group will be invited.

During the whole experiment and once a month, the participants in the action group will receive remote help from an expert in quality improvement methodologies, through teleconferences and e-mails; an electronic forum will be set up in which participants will be able to share their experiences, exchange solutions and documentation (benchmark), ask questions concerning the improvement projects they are carrying out. At the end of the second year of the experiment, all the participating Diabetic Units will present their quality improvement ventures, and the outcomes obtained by the two groups will be compared.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Control of cardiovascular risk factors:

1. Patients taking cholesterol-lowering drugs with low density lipoprotein cholesterol (C-LDL) greater than 100 mg/dl/total number of patients with C-LDL greater than 100 mg/dl
2. Patients undergoing anti-hypertension treatment with pulmonary arterial (PA) pressure greater than 140/90 mmHg/total number of patients with PA pressure greater than 140/90 mmHg

Prescription of anti-aggregant drugs:

3. Patients undergoing anti-aggregant platelet treatment/total number of patients

Primary outcomes will be assessed after 1 year and after 2 years from the start of the study.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/06/2009

Completion date

31/12/2011

Eligibility

Key inclusion criteria

1. Diabetes Units that use an electronic clinical record
2. Diabetes Units included in the list of centres taking part in production of the AMD Annals (AMD Annals. Diabetes care: quality indicators of diabetes care in Italy - <http://www.infodiabetes.it/annali/index.asp>), that offer the first representation of the practical efficacy level of the care provided by diabetology centres

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Has already taken part in quality improvement studies of the type and intensity of this one
2. Located in an area adjacent to that of enrolled Diabetes Units, excluding the worst classified Diabetes Unit

Date of first enrolment

01/06/2009

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Italy

Study participating centre

Via Amendola 2

Reggio Emilia

Italy

42100

Sponsor information

Organisation

Italian Association of Clinical Diabetologists (Associazione Medici Diabetologi [AMD]) (Italy)

Sponsor details

viale Carlo Felice 77

Roma

Italy

00185

+39 067 000 599

segreteria@aemmedi.it

Sponsor type

Research organisation

Website

<http://www.aemmedi.it/>

ROR

<https://ror.org/0451etm15>

Funder(s)**Funder type**

Research organisation

Funder Name

Italian Association of Clinical Diabetologists (Associazione Medici Diabetologi [AMD]) (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