# Effectivity of the Austrian Disease Management Programme for diabetes regarding metabolic control and risk profile

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>	
06/06/2007	No longer recruiting	☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
12/07/2007	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
23/02/2012	Nutritional, Metabolic, Endocrine		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

Prof Andreas Sönnichsen

### Contact details

Strubergasse 21 Salzburg Austria A-5020

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** DW-7111-12570

# Study information

### Scientific Title

# Acronym

**EADMP** 

# **Study objectives**

The Austrian Disease Management Programme for Diabetes aims to improve metabolic control and cardiovascular risk profile in patients with diabetes mellitus type two. It involves structured care, patient guidance, patient reminders, physician reminders, physician education.

# Hypothesis:

The Austrian Disease Management Programme for Diabetes improves metabolic control and cardiovascular risk profile in patients with diabetes mellitus type two.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Approval received from the Ethics Commission of the Province of Salzburg, Austria on the 28th February 2007 (ref: 415-E779/2-2007).

# Study design

Cluster randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

GP practice

# Study type(s)

Quality of life

# 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 mellitus type two

# **Interventions**

The Austrian Disease Management Programme for Diabetes involves the following:

### Structured care:

Physicians are encouraged to use standard documentation and a checklist of control examinations that are appropriate to current guidelines.

# Patient guidance:

- 1. Regular doctors visits (at least every three months)
- 2. Patient education provided by a diabetes counsellor/nurse and/or physicians specifically trained in patient education in diabetes; four modules of 135 minutes each on the following topics:
- 2.1. General information about diabetes
- 2.2. Methods of metabolic control (glucose self-control)
- 2.3. Medication for diabetes
- 2.4. Nutrition/diet
- 2.5. Diabetic foot syndrome
- 2.6. Importance of physical activity
- 2.7. Cardiovascular risk factors
- 2.8. Micro- and macro-angiopathy

Given once at the beginning of the DMP and repeated at least once every three years.

### Patient reminders:

Letter of information that patient should visit his doctor and discuss appropriate steps, administered by the Salzburg Public Health Insurance.

# Physician reminders:

Letter of information that patient should be invited to visit and which steps should be taken, administered by the Salzburg Public Health Insurance.

# Physician education:

10 hours of Continuous Medical Education (CME) provided by the Department of Diabetology of the Paracelsus University Hospital - Salzburger Landeskliniken and the Institute of General Practice, Family Medicine and Prevention at the beginning of DMP on current guidelines and management of diabetes mellitus type two; information about the DMP.

The DMP will be run for one year for the randomised trial, however continuation is planned.

# **Intervention Type**

Other

### Phase

**Not Specified** 

# Primary outcome measure

The following will be assessed at baseline and after one year (i.e. at the end of the trial):

- 1. HbA1c
- 2. Number of days hospitalised
- 3. Percentage of physical and laboratory examinations according to current guidelines

# Secondary outcome measures

The following will be assessed at baseline and after one year (i.e. at the end of the trial):

- 1. Cardiovascular risk profile
- 2. Weight reduction
- 3. Smoking cessation
- 4. Improved knowledge about diabetes
- 5. Improved quality of life (measured using the EuroQoL [EQ-5D] questionnaire)
- 6. Improved patient satisfaction

# Overall study start date

01/07/2007

# Completion date

31/10/2008

# Eligibility

# Key inclusion criteria

- 1. Patients with diabetes mellitus type two (American Diabetes Association [ADA]/World Health Organisation [WHO] criteria)
- 2. Aged greater than 18 years

# Participant type(s)

**Patient** 

# Age group

Adult

# Lower age limit

18 Years

# Sex

Both

# Target number of participants

1200

# Key exclusion criteria

- 1. Dementia
- 2. Psychiatric illness
- 3. Malignant tumour

# Date of first enrolment

01/07/2007

# Date of final enrolment

31/10/2008

# Locations

# Countries of recruitment

Austria

# Study participating centre

# Strubergasse 21

Salzburg Austria A-5020

# Sponsor information

# Organisation

Salzburg Public Health Insurance (Salzburger Gebietskrankenkasse [SGKK]) (Austria)

# Sponsor details

Fabergasse 19
Salzburg
Austria
A-5020
marlies.dicklberger@sgkk.at

# Sponsor type

Industry

# Website

http://esv.sgkk.at

# Funder(s)

# Funder type

Industry

# **Funder Name**

Salzburg Public Health Insurance (Salzburger Gebietskrankenkasse [SGKK]) (Austria)

# **Funder Name**

Investigator funding

# **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	05/11/2010		Yes	No