

# EUropean study on Care and Complications in patients with type 2 Diabetes in Primary Care - Pilot study

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To test the feasibility of the set-up and logistics of the EUCCLID study.1. To assess quality indicators of clinical DM2 care2. To perform questionnaires on quality of life and psychological well-being in DM2 patients in various European countries3...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Glucose metabolism disorders (incl diabetes mellitus)
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON30942

### Source

ToetsingOnline

### Brief title

EUCCLID-Pilot

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)

### Synonym

diabetes

### Research involving

Human

### Sponsors and support

**Primary sponsor:** EASD Study Group on Primary Care Research in Diabetology, under auspices of Primary Care Diabetes Europe

**Source(s) of monetary or material Support:** Primary Care Diabetes Europe stelt een

bedrag van  $\approx$  12000 ter beschikking;dit is het totale budget van de studie

## Intervention

**Keyword:** diabetic complications, primary care, quality of care, type 2 diabetes

## Outcome measures

### Primary outcome

A EUCCLID-CP: quality indicators of clinical diabetes care

B EUCCLID-PP: quality of life (EuroQol EQ-5D) and well-being (WHO-5)

C EUCCLID-GPP: primary care physician\*s perception of the barriers to delivery of effective diabetescare in general practice. All participating primary care physicians will be asked to complete a questionnaire on barriers (Barriers to Diabetes Care Tool) towards the delivery of effective primary diabetes care.

### Secondary outcome

Not applicable

## Study description

### Background summary

Diabetes is one of the commonest chronic diseases managed in primary care. Despite diabetes being a common condition, there is lack of representative epidemiological data relating to its management, complications and long-term follow-up. There are only a few studies that have investigated international (European) differences. The EUCCLID study is a large European study comparing the quality of DM2 care, as experienced by patients and GPs, and the prevalence of complications of DM2 in 12 European countries.

### Study objective

To test the feasibility of the set-up and logistics of the EUCCLID study.

1. To assess quality indicators of clinical DM2 care
2. To perform questionnaires on quality of life and psychological well-being in

DM2 patients in various European countries

3. To test a questionnaire on primary care physicians' perception of the barriers to delivery of effective diabetes care in general practice.

## **Study design**

Cross-sectional survey in 12 European countries comprising three parallel studies:

A EUCCLID-CP: a study on actual clinical practice (CP)

B EUCCLID-PP: a study on patient\*s perspective (PP)

C EUCCLID-GPP: a study on general practitioner\*s perspective (GPP)

As such a study in so many countries is a huge undertaking, the EUCCLID Pilot study will test the feasibility of the set-up and logistics. The protocol, questionnaires and logistic processes of the EUCCLID study will be refined based on the results of this pilot study.

## **Study burden and risks**

The burden and risks associated with the study are minimal. It will consist of one visit (30-40 minutes) and one venapuncture. The only risk is the possible occurrence of a small bruise at the site of venapuncture.

## **Contacts**

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients will be included if they are known with type 2 diabetes, because of

- a diagnosis according to WHO-criteria, or
- according to a former clinical diagnosis resulting in the prescription of oral hypoglycaemic agents (OHAs) for at least 6 months with or without insulin, or
- according to a former clinical diagnosis resulting in a dietary advice (Note: diagnosis of DM2 should be 100% sure; if GP is in doubt patient should not be included!), or
- when starting insulin mono-therapy above age 35 (at least 1 year insulin use)

AND

- if they are mainly under GP care for treatment of their diabetes (to be decided by the GP).
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### Exclusion criteria

- Type 1 diabetes mellitus
- Diabetes of pregnancy
- Serious mental illness (such as Psychotic illness or dementia)
- Any other reason why a questionnaire in national language cannot be completed (such as language barrier)
- Unable to give written informed consent

## Study design

## Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 05-02-2008

Enrollment: 10

Type: Actual

## Ethics review

Approved WMO

Date: 11-09-2007

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

**Register**

CCMO

**ID**

NL17773.041.07