Cognitive Impairment in Diabetes

Published: 30-05-2012
Last updated: 28-04-2024

Overall aimThe ultimate goal of our studies is to optimize treatment and reduce treatment related complications in patients with diabetes and cognitive impairmentOur specific objectives are to:1. assess the validity of two self-administered...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON39732

Source
ToetsingOnline

Brief title
COG-ID

Condition

- Diabetic complications
- Dementia and amnestic conditions

Synonym
adult onset diabetes mellitus, type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: subsidie EFSD Mental Health

Intervention

Keyword: Cognitive functioning, primary care, type 2 diabetes

Outcome measures

Primary outcome

The main study outcome is a diagnosis of cognitive impairment, defined as either MCI or dementia, regardless of the underlying etiology. The diagnosis will be established at the memory clinic at a multidisciplinary team meeting with a rigorous standardized work-up and according to internationally accepted diagnostic criteria. With this outcome we can calculate the accuracy of the screening instruments and the GP evaluation.

Secondary outcome

Secundary outcome of the study will be a a detailed characterisation (cognitive profile, brain MRI, diagnosis) of a population based sample of patients with T2DM and cognitive impairment. Furthermore, we will examine the effect of the diagnostic procedure on diabetes care and patients* quality of life six and twenty-four months after a diagnosis of cognitive dysfunction.

Study description

Background summary

Type 2 diabetes (T2DM) is associated with an increased risk of cognitive impairment, including dementia. Cognitive impairment is often undiagnosed. This is an important problem since cognitive impairment in T2DM is known to be associated with impaired self management and an increased incidence of diabetes-related complications. These problems may be reduced by improving care and social support in people with established cognitive impairment. Unlike other diabetic complications, cognitive impairment is not yet routinely evaluated in daily practice. The establishment of a reliable and efficient test is an essential first step in the early detection and management of cognitive impairment in T2DM

Study objective

Overall aim
The ultimate goal of our studies is to optimize treatment and reduce treatment related complications in patients with diabetes and cognitive impairment

Our specific objectives are to:
1. assess the validity of two self-administered cognitive test instruments to detect cognitive impairment in older patients with T2DM in a primary care setting and select the optimal instrument
2. assess the diagnostic accuracy of a standardised GP evaluation in detecting unrecognised cognitive impairment in patients with T2DM
3. estimate the accuracy and efficiency of the combination of the optimal instrument with the GP evaluation

Secondary objective:
4. provide a detailed characterisation (cognitive profile, brain MRI, diagnosis) of a population based sample of patients with T2DM and cognitive impairment
5. to examine the effect of the diagnostic procedure on diabetes care and patients* quality of life six and twenty-four months after a diagnosis of cognitive impairment

Study design

The Cognitive Impairment in Diabetes study (COG-ID) will include 228 people aged >=70 with T2DM. These people will be recruited from participating general practices and are diagnosed with T2DM but not known with cognitive impairment. All participants will undergo an evaluation including two self-administered instruments (*Test Your Memory* and *Self-Administered Gerocognitive Examination*) and a standardised assessment for cognitive impairment by a general practitioner (GP), including a Mini Mental State Examination (MMSE). In addition, a quality of life and depressive symptom questionnaire (SF-36 and CES-D) will be filled out. All participants suspected of cognitive impairment (on either cognitive test instrument or the GP assessment) and a random sample of 30% of participants without suspicion of cognitive impairment will be referred to the memory clinic in the UMCU, where a medical examination, neuropsychological examination and MRI will be performed. At the memory clinic the main outcome (i.e. presence or absence of cognitive impairment) will be determined, defined as a clinical diagnosis of either mild cognitive impairment (MCI) or dementia. These diagnoses will serve as reference standard. Based on the reference standard the outcome of the cognitive test instruments will be classified as true or false positive and true or false negative and the diagnostic accuracy of the cognitive test instruments, separate and combined, will be examined.
The results will be communicated to the GP and patients according to a

predefined protocol. In case of a diagnosis of cognitive impairment the GP is suggested to adjust the diabetes regimen. After six and twenty-four months a follow-up questionnaire will be sent to the patient to assess the impact of the study on the quality of life and depressive symptomatology of patients.

Study burden and risks

There are no health risks associated with the procedures and techniques used. A diagnosis of MCI or, even more so, dementia can have substantial impact on patients and their relatives. Nevertheless, it is important to emphasize that these diagnoses can only be established if the patient and/or the relatives themselves express serious cognitive complaints. Hence, although the patient or relatives might be in denial, the diagnosis will generally not come as a surprise. Often the diagnosis will help to understand the cause of complaints and insecurities that have already bothered people for a long time.
The diagnosis of dementia or MCI will be established according to internationally accepted criteria, at a specialist clinic. In this setting the risk of false positive dementia diagnosis is minimal. In case of doubt, no diagnosis will be established, and the patient will be offered a reevaluation after 6 to 12 months.
The results of the study will contribute to an earlier detection of cognitive impairment in patients with T2DM and thus help to improve treatment for these patients in the future. Direct implementation of this diagnostic procedure in all general practices in the Netherlands or abroad seems feasible.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnosis of type 2 diabetes and aged 70 years or older

Exclusion criteria

- Patients with a previous diagnosis of cognitive problems or dementia
- Patients unable or unwilling to give written informed consent
- Not capable of writing and reading in Dutch

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2012
Enrollment:	228
Type:	Actual

Ethics review

Approved WMO Date:	30-05-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-11-2014
Application type:	Amendment
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	ID
CCMO	NL37478.041.11