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The correlation between the quality of life using the World Health Organization Quality of Life Assessment questionnaire (WHOQOL-BREF) and Glycated Haemoglobin (HbA1c) in patients with diabetes

Submission date
24/05/2018

Recruitment status
No longer recruiting

Registration date
05/06/2018

Overall study status
Completed

Last Edited
31/12/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients with diabetes have a lower quality of life compared with individuals without diabetes in the same age group, and the quality of life in diabetes patients continues to deteriorate with disease progression and complications. Diabetes imposes a considerable economic burden on the society as a whole, and on individual patients and their families. Reduced quality of life in diabetes patients through disability, diabetes complications and loss of productivity may negatively influence economic progress. Better quality of life may also improve adherence to diabetes therapy and also may lead to better glucose control and fewer complications. This study will examine the correlation between glucose control and the WHOQOL-BREF quality of life score and also the relationship between the quality of life score and the Hba1C value.

Who can participate?
Patients aged 18 to 80 with diabetes type 1 or type 2

What does the study involve?
Quality of life is evaluated using the WHOQOL-BREF questionnaire form. Glucose control is measured using HbA1c value in the medical notes and yype of diabetes treatment is measured using outpatient data and medical notes.

What are the possible benefits and risks of participating?
The aim of this study is to measure and improve quality of life for diabetes patients in the diabetes outpatient clinic. It is a survey using a questionnaire and there will be no risks for the participants.

Where is the study run from?
Melk General Hospital (Austria)

When is the study starting and how long is it expected to run for?
February 2018 to February 2020

Who is funding the study?
Melk General Hospital (Austria)

Who is the main contact?
Dr Nawras Altaie

Contact information

Type(s)
Public

Contact name
Dr Nawras Al-taie

Contact details
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Additional identifiers

Protocol serial number
GS1-EK-4/493-2017

Study information

Scientific Title
The correlation between the quality of life using the World Health Organization Quality of Life Assessment questionnaire (WHOQOL- BREF) and Glycated Haemoglobin (HbA1c) in patients with diabetes

Study objectives
This study will examine the correlation between glycemic control and WHOQOL-BREF scale score and also the relationship between the quality of life score and the HbA1C value. This study will examine the internal consistency, responsiveness and the reliability of the WHOQOL-BREF scale and its four domains (Physical health, Physical health, Social relationships and Environment) for patients living with diabetes in Austria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board for the government of Lower Austria region, 21/08/2017, ref: GS1-EK-4/493-2017

Primary study design

Observational

Study design
Observational cross-sectional study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Diabetes mellitus type 1 and type 2

Interventions
The data is collected over 6-12 months. Quality of life is assessed using the WHOQOL-BREF questionnaire.
The latest HbA1c is documented for each patient in their WHOQOL-BREF questionnaire form.
Patients will be further subdivided into different groups according to their diabetes therapy (the patient should be on this therapy for at least 6 months).

Intervention Type
Other

Primary outcome(s)
1. Quality of life, measured using the German version of WHO-BREF at 2 years
2. Glycemic control, measured using HbA1c value in the medical notes at 2 years

Key secondary outcome(s)
Type of diabetes treatment, measured using outpatient data and medical notes at 2 years

Completion date
01/02/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 24/08/2018:
1. Patients with diabetes both type 1 and type 2
2. Age range between 18 and 80 years old

Previous exclusion criteria:
1. Patients with diabetes both type 1 and type 2
2. Age range between 18 and 65 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
223

Key exclusion criteria
Current exclusion criteria as of 24/08/2018:
1. Gestational diabetes
2. Patients younger than 18 and older than 80

Previous exclusion criteria:
1. Gestational diabetes
2. Patients younger than 18 and older than 65

Date of first enrolment
01/03/2018

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
Austria

Study participating centre
Melk General Hospital
Melk
Austria
3390

Sponsor information

Organisation
Landesklinikum Melk

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Melk General Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nawras Al-Taie.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/12/2019	31/12/2019	Yes	No
Results article	results	01/09/2011	31/12/2019	Yes	No