ISRCTN50008265 https://doi.org/10.1186/ISRCTN50008265

Consequences of reducing hypoglycemia-inducing glucose-lowering medication (medication that lowers glucose (sugar) levels in the blood and can cause low blood sugar) in people with type 2 diabetes of 70 years or older

Submission date 02/03/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/03/2023	**Overall study status** Ongoing	
Last Edited 29/07/2024	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

Older people with type 2 diabetes have a higher risk of health problems like low blood sugar, disability, and death from diabetes medications. In the Netherlands, a study found that many hospital admissions of older people were caused by low blood sugar from insulin or sulfonyl urea drugs. Low blood sugar also increases the risk of falls, fractures, and dementia. Frailty can make diabetes worse and increase the risk of low blood sugar even more. Guidelines suggest being less strict about controlling blood sugar in older people with diabetes, but many doctors still give too much medication. They may not know how to reduce medication safely or worry about the risks of high blood sugar. To make sure it's safe to reduce medication, more research is needed. This study aims to see if reducing medication for older people with diabetes is safe and improves quality of life. It will also look at how to do this in practice and if it saves money.

Who can participate?

People with type 2 diabetes over 70 years of age who are using insulin or sulfonyl urea derivates and have Hba1c levels below the suggested thresholds of the 2018 Diabetes guideline of the Dutch Society of General Practitioners.

What does the study involve?

Reducing medication until acceptable levels of Hba1c have been reached. The reduction of the medication and the selection of the threshold is defined in a shared decision making procedure between patient and health care professional. Patients who indicate willingness after a written invitation will be invited to fill in 6-monthly questionnaires during a follow up period of five years (five questionnaires) and might be invited for an interview.

What are the possible benefits and risks of participating?
Possible benefits: reduction of hypoglycemic episodes with negative consequences
Possible risks: increase of hyperglycemic episodes with negative consequences

When is the study starting and how long is it expected to run for?
January 2021 to July 2026

Who is funding the study?
The study is funded by ZonMW, The Netherlands organisation for health research and development.

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Zonmw file number 848018102

Study information

Scientific Title
Consequences of reducing hypoglycemia-inducing glucose-lowering medication in people with type two diabetes: an open cluster controlled intervention study comparing the implementation of a deprescribing program in primary care practises versus usual care

Acronym
OMED2

Study objectives
Reducing hypoglycemia inducing glucose lowering medication in people of 70 years or older in order to meet the criteria of the 2018 guideline of the Dutch Society of General Practice does not lead to increased registered medical problems by the GP that are are -according to a delphi procedure with GP's - related to hyperglycemia or hyperglycemia, reduced quality of life or increased cost.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics committee of Amsterdam UMC, location VU deemed that the study did not fall under the reserach with human subjects act (correspondence number 2021.0231) after wich the Directory Board of Amsterdam UMC, location VU approved of the study.

Study design
Open cluster randomized study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Complications of type 2 diabetes

Interventions
The intervention consists of an implementation program aimed at reducing glucose-lowering medications in people of 70 years of age that have too low Hba1c according to the 2018 guideline of the Dutch Society of General Practitioners and are treated with potentially hypoglycaemia-inducing glucose-lowering medication. The study compares the intervention to usual care.
The implementation program consists of digital training sessions, a digital algorithm to select the potential patients for the program, supporting practice visits by specially trained medical students or research assistants and an expert panel consisting of a GP expert in Diabetes, a pharmacist, a diabetologist and a geriatrician.
The control practices receive an implementation program in which the prescription of SGLT2 inhibitors or GLP1 agonist is stimulated in patients younger than 70 years with manifest diabetes complications.

Before practices receive the training program for the study which depends on the intervention allocation, participating practices will be randomly allocated to the intervention, or control condition. Randomisation will be performed by a researcher blinded to characteristics of the practices using a digital tool. Practices starting the monthly training course are stratified by practice size (two strata), to ensure equally sized groups. Patients will be allocated to either one

of the treatment conditions, based on the practice where they are listed. Blinding of patients, GPs and practice nurses to treatment allocation is not possible due to the nature of the intervention.

Intervention Type
Mixed

Primary outcome measure
Two year follow up count of all ICPC coded reasons of encounter registered in the routine care electronical register of the GP practice that are potentially related to hypoglycemia selected in a Delphi procedure by three GP's.

Secondary outcome measures
1. Two year follow up count of all ICPC coded reasons of encounter selected in a Delphi procedure by three GP's registered in the routine
care electronic register of the GP practice that are potentially related to hyperglycemia .
2. Two year follow up count of all ICPC coded reasons of encounter selected in a Delphi procedure by three GP's registered in the routine
care electronic register of the GP practice that are potentially related to either hyperglycemia or hypoglycemia.
3. Quality of life, measured every six months using the EQ5D-5L and EQ5D-VAS as indicated by patients agreeing to fill in 6-monthly questionnaires.
4. Blood pressure measurements and laboratory measurements registered in the routine care electronic digital file of the GP: Hba1c, fasting
plasma glucose measurements.
5. Number of medication prescriptions registered in the EMR
6. Hospital admissions, visits to emergency departments (hospital or primary care) and nursing home admissions as indicated by patients agreeing to fill in 6-monthly questionnaires.
7. Health care and patient cost including medical prescription data will be analyzed from the societal perspective based on 6 monthly patient questionnaires.
8. Cognitive evaluation using the Minicog questionnaire if deemed necessary by the health care professionals and registered in the medical file.
9. Process analysis: for the purpose of studying the implementation, we shall study an extraction of the EMR of the patients who were selected for DDP in the intervention study. As part of the analysis all free text in the GP file will be extracted and after erasing all potential identifying information, will be studied as well. Using the administrative labels regarding inclusion and participation in the DDP, we will be able to deduce the aspects that caused enrollment or exclusion in the DDP intervention and how it was performed and which medical interventions (medication changes, lab measurements) were done. We shall also organize interviews with GP’s, PN’s. A random number of 20 study participants will be approached for an interview during the study to study whether we might improve the program (training, materials) further.

Overall study start date
01/01/2021

Completion date
01/07/2026

Eligibility

Key inclusion criteria

1. Age 70 years or older
2. Having type 2 diabetes
3. Using insulin or sulfonyl urea derivative drugs
4. Recent Hba1c below 54 mmol/ mol or if deemed fragile by the GP practice below 58mmol/mol

Participant type(s)
Patient

Age group
Senior

Lower age limit
70 Years

Sex
Both

Target number of participants
We expect to include in total 404 participants in 74 clusters

Key exclusion criteria
Previously having indicated to be not willing to participate in studies using routine care electronic data

Date of first enrolment
13/03/2023

Date of final enrolment
13/03/2024

Locations

Countries of recruitment
Netherlands

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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/05grdyy37

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in high impact peer reviewed journals and in peer reviewed journals read by practitioners and practice nurses

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/07/2024	29/07/2024	Yes	No