

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of Self Monitoring of Blood Glucose (SMBG) on glycosylated hemoglobin level in elderly patients with type 2 diabetes mellitus

Protocol summary

Study aim

Comparison of the effect of self-assessment of blood glucose on glycosylated hemoglobin levels in elderly patients with type 2 diabetic

Design

In this study, 150 elderly patients with type 2 diabetes will be divided in to two groups randomly. Intervention group are elderly patients with type 2 diabetes who perform self-assessment. and control group are elderly patients who do not perform self assessment.

Settings and conduct

In this randomized control trial , 150 elderly patients with type 2 diabetes will be divided in to two groups randomly regard to random block and table method. Intervention group are elderly patients with type 2 diabetes who perform self-assessment. and control group are elderly patients who do not perform self assessment. Physicians and data collector will be unaware of self assessment.

Participants/Inclusion and exclusion criteria

Inclusion criteria are type 2 diabetes, agreement to participate in the research and Glycosylated hemoglobin between 7 and 9%. Exclusion criteria are other chronic diseases including cancer, renal failure, hepatic and heart failure-2 inflammatory diseases, rheumatoid arthritis, Major Depression, other endocrine disorders, Cushing's syndrome and hematologic disorders.

Intervention groups

Intervention group: elderly patients with type 2 diabetes who perform self-assessment. Control group: Elderly diabetic patients who do not perform self-assessment of blood glucose.

Main outcome variables

Glycosylated hemoglobin (HbA1C)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171225038055N1**

Registration date: **2018-06-05, 1397/03/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-05, 1397/03/15**

Update count: **0**

Registration date

2018-06-05, 1397/03/15

Registrant information

Name

Atousa Ariafar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 3512

Email address

ariafara2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2018-07-20, 1397/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Self Monitoring of Blood

Glucose (SMBG) on glycosylated hemoglobin level in elderly patients with type 2 diabetes mellitus		Street address Asadabadi blvd; sabzevar	
Public title Self Monitoring of Blood Glucose (SMBG) in elderly patients with type 2 diabetes mellitus		City Mashhad	
Purpose Treatment		Province Razavi Khorasan	
Inclusion/Exclusion criteria Inclusion criteria: Type 2 diabetes agreement to participate in the research Glycosylated hemoglobin between 7 and 9% Exclusion criteria: Infection with other chronic diseases including cancer, severe renal failure, severe liver and heart failure Inflammatory diseases, including rheumatoid arthritis Major Depression Other endocrine disorders, including Cushing's Blood disorders and the need for several blood transfusion		Postal code 9613873119	
Age From 60 years old		Approval date 2018-01-03, 1396/10/13	
Gender Both		Ethics committee reference number IR.MEDSAB.1396.118	
Phase 2-3		Health conditions studied <u>1</u> Description of health condition studied Diabetes ICD-10 code E11 ICD-10 code description Type 2 diabetes mellitus	
Groups that have been masked • Participant • Care provider • Outcome assessor • Data and Safety Monitoring Board		Primary outcomes <u>1</u> Description Glycosylated hemoglobin Timepoint Before the intervention, 120 days after self-assessment of blood glucose Method of measurement The test for hemoglobin A1c will be performed by chromatography.	
Sample size Target sample size: 150		Secondary outcomes empty	
Randomization (investigator's opinion) Randomized		Intervention groups <u>1</u> Description Intervention group: Self-assessment of blood glucose in elderly diabetic patients treated with insulin . Category Behavior	
Randomization description Patients referred to diabetes clinic in Sabzevar will be randomly divided into two groups based on random block method and tables.		<u>2</u> Description Control group: Elderly diabetic patients who do not perform self-assessment of blood glucose. Category Behavior	
Blinding (investigator's opinion) Single blinded		Recruitment centers	
Blinding description Physicians and data collector will be unaware of self assessment.			
Placebo Not used			
Assignment Parallel			
Other design features			
Secondary Ids empty			
Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Sabzevar University of Medical Sciences			

1

Recruitment center

Name of recruitment center

Sabzevar Diabetes Clinic

Full name of responsible person

atousa ariafar

Street address

asadabadi street; 1specefic clinic;

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshteh ghorat

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shohadai hasteii Blvd., Sabzevar University of Medical Sciences

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VCRResearch@medsab.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

atousa ariafar

Position

Non-faculty

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Atousa Ariafar

Position

Head nurse

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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Mashhad

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The mean values of glycosylated hemoglobin, demographic variables and their relationship will be shared in the final article.

When the data will become available and for how long

Start the access period immediately after printing the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

The type of analysis, method of use and results should be specified.

From where data/document is obtainable

Author of the article and author of the first article
assarroudia@medsab.ac.ir ariafara2@mums.ac.ir

What processes are involved for a request to access data/document

send mail Detailed explanation of the required data The reason for the data requirement

Comments