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Blood vessel problems in people with prediabetes and diabetes who have healthy heart arteries

Submission date
21/09/2024

Recruitment status
No longer recruiting

Registration date
23/09/2024

Overall study status
Completed

Last Edited
06/11/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Diabetes mellitus (DM) is a global health issue associated with increased heart disease risk. Endothelial dysfunction (narrowed blood vessels) is a known precursor to atherosclerosis (buildup of substances on blood vessel walls) and heart disease, and its role in DM complications is well-documented. There is limited information on endothelial (blood vessel wall) function in prediabetic patients evaluated using flow-mediated dilation (FMD), and studies have not excluded patients with known atherosclerosis or coronary artery disease. This study aimed to evaluate endothelial function using flow-mediated dilation from the brachial (upper arm) artery of DM and prediabetes patients who had normal coronary arteries.

Who can participate?
Patients aged 21-80 years evaluated in the Cardiology outpatient clinic who are found to have normal coronary arteries on coronary angiography, including patients with DM, prediabetes, and non-diabetics

What does the study involve?
The study involves the measurement of flow-mediated dilation of participants according to the established standard methods. The participants are divided into three groups according to their blood sugar status which is determined by measurement of blood glucose levels in the fasting state and after glucose loading.

What are the possible benefits and risks of participating?
The endothelial function of the brachial arteries of the participants will be measured using a noninvasive method. This will enable further determination of heart disease risk and preventive action. The glucose tolerance test and measurement of FMD using ultrasound from the brachial artery carries no risk for the participants.

Where is the study run from?
Ankara Guven Hospital (Türkiye)

When does the study start and how long is it expected to run for?
May 2008 to December 2010

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
GHE 190

Study information

Scientific Title
Evaluation of endothelial dysfunction in prediabetes and diabetes mellitus in patients with normal coronary arteries using flow-mediated dilation of brachial artery

Study objectives
Diabetes mellitus (DM) is an important global pandemic disease and is associated with an increased incidence and mortality of cardiovascular disease. Endothelial dysfunction is considered a precursor to atherosclerosis and cardiovascular disease (CVD) and the role of endothelial dysfunction in the pathogenesis of both microvascular and macrovascular complications is well-documented in patients with DM. Prediabetes is an important diagnosis, enabling physicians to implement measures to prevent the progression to DM and its related complications or to slow the disease process. Evaluating endothelial function in prediabetic

patients may allow for the early detection and treatment of issues before further complications arise. One of the most widely used non-invasive methods for assessing endothelial function in arteries is flow-mediated dilation (FMD) of the brachial artery. The relationship between the presence and severity of coronary artery disease and the degree of endothelial dysfunction is well established. Therefore, assessing endothelial function in a prediabetic population without excluding the presence of coronary artery disease presents limitations in demonstrating a causal relationship between endothelial dysfunction and prediabetes. Thus, this study aimed to evaluate the endothelial functions using FMD from the brachial artery of DM and prediabetes patients who had normal coronary arteries.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/12/2008, Ankara Guven Hospital Ethics Committee (Ankara Guven Hastanesi, Kavaklıdere, Simsek Sok. No: 29 Cankaya, Ankara, 06640, Türkiye; +90 (0)3124572525; guven@guven.com.tr), ref: 190

Study design
Non-randomized study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Endothelial dysfunction in patients with diabetes and pre-diabetes with normal coronary arteries

Interventions
Patients evaluated in the Cardiology outpatient clinic who are found to have normal coronary arteries on coronary angiography will be included in the study. Diabetes and pre diabetes will be diagnosed according to American Diabetes Association criteria. Participants will be grouped as diabetic, pre diabetic and normal. Flow mediated dilation will be performed following the guidelines outlined in previously published literature by an investigator proficient in vascular ultrasound techniques.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Flow-mediated dilation is measured by an ultrasound system equipped with a 5-10 MHz linear array transducer from the brachial artery at baseline and after vasodilation, using an ultrasound, taken once per patient

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/12/2010

Eligibility

Key inclusion criteria
1. Patients evaluated in the Cardiology outpatient clinic who were found to have normal coronary arteries on coronary angiography
2. Aged 21-80 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
21 years

Upper age limit
80 years

Sex
All

Total final enrolment
73

Key exclusion criteria
1. A history of previous percutaneous coronary intervention
2. Atrial fibrillation
3. Heart failure
4. More than mild valvular regurgitation
5. Valvular stenosis
6. Uncontrolled hypertension (systolic blood pressure ≥ 160 mmHg and diastolic blood pressure ≥90 mmHg in the last 6 weeks)
7. Cardiomyopathy
8. Chronic kidney or liver disease

Date of first enrolment
25/12/2008

Date of final enrolment
30/10/2010

Locations

Countries of recruitment
Türkiye

Study participating centre
Ankara Guven Hastanesi
Kavaklıdere, Simsek Sok. No: 29 Cankaya
Ankara
Türkiye
06690

Sponsor information

Organisation
Ankara Guven Hospital

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from the corresponding author (Dr İnci Aslı Atar, asliatar@gmail.com, inciasli.atar@saglik.gov.tr)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/11/2024	06/11/2024	Yes	No