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Artificial intelligence to predict cardiovascular risk recurrence in people with type 2 diabetes

Submission date
01/04/2026

Recruitment status
Recruiting

Registration date
23/04/2026

Overall study status
Ongoing

Last Edited
28/08/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with type 2 diabetes have a higher chance of having further heart or blood vessel problems after an initial event. Current tools used by doctors to estimate this risk are limited because they do not include information from many different sources. This study aims to develop a new way to predict future cardiovascular events by combining clinical information, blood tests, genetic data, gut microbiome samples and data from wearable devices. The goal is to create a more accurate prediction tool that could help guide care in the future.

Who can participate?
Adults aged 40 to 70 years with type 2 diabetes who have had a major cardiovascular event in the past 12 months can take part. They must be able to give written consent and use wearable monitoring devices. People with advanced heart failure, chronic dialysis, active cancer, severe infections or blood disorders, uncontrolled psychiatric conditions, significant cognitive problems, or those in other studies that could affect results cannot take part.

What does the study involve?
This is an observational study, meaning participants do not receive any treatment as part of the research. The study involves collecting information from clinical records, blood samples, genetic tests, gut microbiome samples and wearable devices that measure daily activity, heart rate and sleep. Participants will be followed for 24 months to check whether they have new cardiovascular events during this period.

What are the possible benefits and risks of participating?
There is no direct medical benefit for participants. However, the information gathered may help improve future prediction tools for people with type 2 diabetes. The risks are minimal and relate mainly to routine procedures such as blood tests and the inconvenience of wearing a monitoring device. There is no change to usual medical care.

Where is the study run from?
The study is being carried out in Navarra, Spain, through hospital and primary care centres.

When is the study starting and how long is it expected to run for?
April 2026 to December 2029.

Who is funding the study?
Department of Health of the Government of Navarre (Spain)

Who is the main contact?
Mr Alcibiades Segundo Diaz Vera, as.diaz.vera@navarra.es

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Study information

Scientific Title
CARDIO-DIABETES AI: Multimodal machine learning-based risk stratification of cardiovascular recurrence in patients with type 2 diabetes

Acronym
CARDIO-DIABETES AI

Study objectives
This is a prospective observational cohort study in patients with type 2 diabetes and a recent cardiovascular event. The aim is to develop and internally validate a multimodal machine learning model to predict recurrent cardiovascular events in a secondary prevention setting.

The primary outcome is recurrent cardiovascular events over 24 months. The study is justified by the limitations of current risk prediction models, which do not integrate multimodal biological and physiological data.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/08/2025, Research Ethics Committee with Medicines of Navarra (CEIm-NA) (Hospital Universitario de Navarra Irunlarrea 3, Pamplona/Iruña, 31008, Spain; +34 848 422497; ceim@navarra.es), ref: PI_2025/103

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus and cardiovascular disease (secondary prevention of cardiovascular events)

Interventions
Current methodology as of 25/08/2026:
This is an observational study with no intervention and data collection only, including clinical, biological and wearable-derived variables. A total of 250 patients aged 40–70 years will be recruited from hospital and primary care settings in Navarra, Spain.

Clinical, genomic and polygenic risk score data, gut microbiome and metabolomic data, inflammatory and oxidative-stress biomarkers, NMR-based lipid and lipoprotein data, and longitudinal wearable-derived data will be collected and integrated for multimodal prediction modelling.

Previous methodology:
Observational study with no intervention. Data collection only, including clinical, biological and wearable-derived variables.

A total of 250 patients aged 40–70 years will be recruited from hospital and primary care settings in Navarra, Spain. Clinical, biological and wearable data will be collected.

Intervention Type
Other

Primary outcome(s)
1. Recurrent major cardiovascular event, defined as a composite of acute coronary syndrome, atherothrombotic stroke, arterial revascularisation, and cardiovascular death, measured using clinical assessment and electronic health record verification at the 24-month follow-up period

Previous primary outcome as of 25/08/2026:
Recurrent major adverse cardiovascular events (MACE), measured using clinical assessment and electronic health record verification as a composite outcome (acute coronary syndrome, atherothrombotic stroke, vascular revascularisation or cardiovascular death) at 24 months

Key secondary outcome(s)
1. All-cause mortality measured using individual components of major adverse cardiovascular events at 24 months

2. Individual components of major adverse cardiovascular events measured using clinical assessment and electronic health record verification at 24 months

3. Incidence of acute coronary syndrome, atherothrombotic stroke, arterial revascularisation, and cardiovascular death, measured using scheduled clinical assessments and electronic health record verification at 6 monthly time points throughout the 24-month follow-up period

4. All-cause mortality, measured using scheduled clinical assessments and electronic health record verification at 6 monthly time points throughout the 24-month follow-up period

Completion date
31/12/2029

Eligibility

Key inclusion criteria
1. Adults aged 40–70 years
2. Confirmed type 2 diabetes mellitus
3. History of a major cardiovascular event within the previous 12 months (including acute coronary syndrome, atherothrombotic stroke or arterial revascularisation)
4. Able to provide written informed consent and willing and able to use wearable monitoring devices

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 25/08/2026:
1. Advanced heart failure requiring palliative care, ventricular assist support or evaluation for heart transplantation
2. Chronic dialysis
3. Long-term home oxygen therapy
4. Active malignancy or life expectancy of less than 3 years
5. Severe haematological disorders
6. Severe active infectious disease
7. Uncontrolled major psychiatric illness
8. Significant cognitive impairment
9. Inability to ensure adequate follow-up
10. Inability or unwillingness to use the study wearable device
11. Participation in another study that could interfere with study outcomes or adherence

Previous key exclusion criteria:
1. Advanced heart failure requiring palliative care or transplant evaluation
2. Chronic dialysis
3. Active malignancy or life expectancy less than 3 years
4. Severe haematological or infectious diseases
5. Uncontrolled psychiatric disorders
6. Significant cognitive impairment
7. Inability to ensure follow-up or comply with wearable device use
8. Participation in other studies that may interfere with the study outcomes

Date of first enrolment
01/09/2026

Date of final enrolment
31/08/2027

Locations

Countries of recruitment
Spain

Sponsor information

Organisation
Navarre Health Research Institute Foundation (IDISNA)

Funder(s)

Funder type

Funder Name
Department of Health of the Government of Navarre

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study may be made available upon reasonable request from Alcibíades Segundo Díaz Vera (alcibiadessegundo.diaz@unavarra.es), subject to applicable ethical, legal, data-protection and institutional requirements. Data potentially available for sharing may include anonymised participant-level data underlying published study results, associated data dictionaries, and analytical code, where such sharing is legally and ethically permissible. Data would become available following publication of the main study results and would remain available in accordance with applicable institutional data-retention policies. Access would be considered for bona fide researchers submitting a scientifically justified proposal for research purposes compatible with the original study objectives and participant consent. Requests would be subject to review and approval by the study investigators and relevant institutional bodies, and a data-use agreement may be required. Directly identifying information will not be shared. Genomic and other potentially re-identifiable data will only be shared where permitted by participant consent, applicable data-protection legislation, ethical approval and institutional policies.

IPD sharing plan summary
Available on request