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Sarcopenia and diabetes in elderly adults with type 2 diabetes

Submission date	Recruitment status	[_] Prospectively registered
01/10/2026	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/10/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/10/2026	Musculoskeletal Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Prevalence and predictors of sarcopenia in elderly adults with type 2 diabetes: an Italian cross-sectional study

Acronym
SARCODIAB

Study objectives

The study conducted at the community diabetes clinic in Cesano Boscone (Milan) aimed to assess the prevalence of sarcopenia in patients with type 2 diabetes mellitus (T2DM) followed at the clinic.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/06/2026, Territorial Ethics Committee Lombardy 3 (via Francesco Sforza 28, Milano, 20122, Italy; +39 (0)255032982; cetlombardia3@policlinico.mi.it), ref: ID 7296 – parere numero 7296_10.06.2026_P_bis

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)

Health condition(s) or problem(s) studied
Sarcopenia in diabetic patients

Interventions
An observational, cross-sectional, retrospective study. Patient data will be extracted from the diabetes medical records held at the center:

Initial functional assessment through two fundamental tests:
1. Handgrip test (manual grip strength): pathological if <32 kg in men and <19 kg in women
2. Chair Stand Test (CST): considered positive if the time required for five lifts from the chair - without aid - exceeds 12 seconds

Instrumental examination:
Only if both tests are positive, a muscle ultrasound of the quadriceps femoris is carried out to objectify the thickness of the muscle itself

BMI indexing:
1. The value of muscle thickness (in cm) is divided by the patient's BMI to obtain the muscle/BMI index
2. Diagnostic cut-offs:
2.1. <1.4 in men
2.2. <1.0 in women

Parameters and tests used:
For patients included in the study, the following parameters were analyzed:
1. T0 blood tests: HbA1c, creatinine
2. Anthropometric evaluations: weight, height, BMI, waist circumference
3. Hypoglycemic therapy in progress

Muscle functional tests:
1. Handgrip Test: evaluation of grip strength (kg)

2. Chair Standing Test (CST): measure of the time needed to perform five lifts from the chair with arms crossed
3. Muscle ultrasound of the quadriceps femoris (carried out if both of the above tests were positive)

Intervention Type
Other

Primary outcome(s)
1. The prevalence of sarcopenia in patients with type 2 diabetes mellitus, measured using patient data extracted from the diabetes medical records held at the center, measured at a single timepoint

Key secondary outcome(s)

Completion date
22/10/2025

Eligibility

Key inclusion criteria
Documented diagnosis of type 2 diabetes in patients aged ≥65 years, or aged <65 years with at least one comorbidity associated with an increased risk of sarcopenia, including: CKD, RD, PAD, CVD, PN, obesity, chronic physical inactivity, metabolic liver disease, heart failure, depression, transplantation, steroid therapy, significant weight loss, osteoarthritis, cognitive decline, neurological diseases, history of cerebrovascular events, recent hospitalization, recurrent falls, chronic tiredness, fatigue, and progressive movement limitations.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
60 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
1000

Key exclusion criteria
1. Unstable clinical status (acute infections, acute heart or renal failure) or neoplasms
2. Objective inability to perform the required functional tests

Date of first enrolment
01/01/2025

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Ambrosiana Nursing Home in Cesano Boscone, Piazza Monsignor Moneta

Funder(s)

Funder type

Funder Name
Ambrosiana Nursing

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			02/10/2026	No	No