

# Understanding the connection between saliva and muscle loss in older adults

<b>Submission date</b> 21/09/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/10/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/11/2024	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Sarcopenia is a condition that involves the gradual loss of muscle mass, strength, and function. It is linked to adverse outcomes such as falls, hospitalizations, and increased risk of death. Despite its significant impact on ageing populations, effective treatments are limited due to gaps in understanding its underlying causes. While the role of the gut microbiome (bacteria) in sarcopenia has gained attention, the potential influence of other microbial ecosystems, such as the oral (mouth) microbiome, remains underexplored. This study aims to investigate the relationship between sarcopenia and the oral microbiome using a comprehensive multi-omics approach (combining different types of biological data).

### Who can participate?

Caucasian older adults aged 70+ years without diseases interfering with sarcopenia

### What does the study involve?

The study is conducted in three phases:

Phase 1: Analysis to link sarcopenia status (muscle mass, strength, and function) with salivary microbiome composition using multi-omics techniques.

Phase 2: Muscle tissue biopsies (samples) will be analyzed in some of the participants

Phase 3: A 2-year follow-up will track changes in sarcopenia and adverse outcomes (e.g., falls, hospitalizations), with another analysis of saliva and blood samples at the end.

### What are the possible benefits and risks of participating?

Participants will gain insights into their sarcopenia status, receive personalized feedback, and have their blood analysis results shared with their physicians. For those undergoing muscle biopsies, there is a minor risk of pain, bleeding, or infection.

### Where is the study run from?

Ghent University Hospital (Belgium)

### When is the study starting and how long is it expected to run for?

March 2023 to December 2026

Who is funding the study?  
Ghent University Hospital (Belgium)

Who is the main contact?  
Dr Anton De Spiegeleer, anton.despiegeleer@uzgent.be

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Anton De Spiegeleer

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

SaMu: an observational study on the link between salivary omics and muscle ageing (sarcopenia)

### Acronym

SaMu

### Study objectives

The gut microbiome is recognized as a pivotal factor in the pathophysiology of sarcopenia, a condition marked by the accelerated loss of muscle strength, mass and function with ageing. Despite this well-known gut-muscle axis, the potential links between other microbial ecosystems and sarcopenia remain largely unexplored. The oral microbiome has been linked to various age-related health conditions such as rheumatoid arthritis and colorectal cancer. However, its potential association with sarcopenia is unknown. The Saliva and Muscle (SaMu) study seeks to address this knowledge gap.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 20/04/2023, Ghent University Hospital Ethics Committee (Corneel Heymanslaan 10, Ghent, 9000, Belgium; +32 (0)9 332 21 11; ethisch.comite@uzgent.be), ref: BC-1850-AM02

## **Study design**

Multicenter observational cohort study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic, Quality of life

## **Health condition(s) or problem(s) studied**

Sarcopenia

## **Interventions**

The SaMu study consists of three phases aimed at exploring the relationship between the salivary microbiome and sarcopenia in older adults.

### **Phase 1: Cross-Sectional Analysis**

A cohort of 200 participants aged 70+ years will be recruited from community, assisted living, and nursing home settings. The salivary microbiome will be analyzed using shotgun metagenomics, and sarcopenia will be assessed via muscle mass (bioelectrical impedance analysis, calf circumference), muscle strength (grip strength, 5-times-sit-to-stand), and physical performance (walking speed). Additional omic analyses (proteomics, metabolomics, peptidomics) and clinical variables (demographics, health status, blood parameters) will be collected.

### **Phase 2: Mechanistic Sub-Analysis**

An in-depth analysis of muscle tissue (histology, genomics, transcriptomics) will be conducted on a subcohort of 50 participants (25 healthy, 25 severe sarcopenia) to investigate underlying pathways.

### **Phase 3: Longitudinal Follow-Up**

A 2-year follow-up of the initial cohort will include resampling of blood and saliva, alongside tracking secondary outcomes such as falls, hospitalization, and mortality.

For detailed protocols, see De Spiegeleer et al., Journal of Frailty & Aging 2024.

## **Intervention Type**

Other

## **Primary outcome(s)**

Sarcopenia status is evaluated at baseline, as well as after 1 and 2 years. This status is treated as a continuous desirability variable, which is determined by three key components: muscle mass (assessed using bioelectrical impedance analysis), muscle strength (measured through grip dynamometry), and physical performance (evaluated through usual walking speed).

## **Key secondary outcome(s)**

1. Sarcopenia status assessed using European Working Group On Sarcopenia in Older People 2 (EWGSOP2) criteria at baseline, as well as after 1 and 2 years
2. Individual sarcopenia components: muscle mass (assessed via bioelectrical impedance analysis), muscle strength (measured through grip dynamometry), and physical performance (evaluated by usual walking speed) assessed at baseline, 1 year, and 2 years
3. Muscle mass and strength measured through calf circumference 5-times sit-to-stand test at baseline, 1 year, and 2 years
4. Mortality determined through health record reviews and hetero-anamnesis at 1 year and 2 years
5. The number of hospitalisations identified via health record checks and hetero-anamnesis at 1 year and 2 years
6. Quality of life assessed using the SarQoL questionnaire at baseline, 1 year, and 2 years
7. The number of falls recorded through anamnesis and health record checks at 1 year and 2 years
8. The number of fractures tracked via anamnesis and health record checks at 1 year and 2 years
9. The incidence of institutionalisation determined through anamnesis and hetero-anamnesis at 1 year and 2 years

## **Completion date**

31/12/2026

## **Eligibility**

### **Key inclusion criteria**

1. Caucasian
2. Aged 70 years or older

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Senior

### **Lower age limit**

70 years

### **Upper age limit**

120 years

### **Sex**

All

### **Key exclusion criteria**

1. Known presence of interfering neuromuscular or osteoskeletal conditions (possibly leading to false-positive diagnosis of sarcopenia), such as stroke without full recuperation, Parkinson's disease, spinal compression, or functional anomaly of the hands or legs

2. >10% total body weight loss over the past 6 months
3. Active malignant neoplasia
4. Status post radiation therapy in the head-neck region
5. Exposure to immunosuppressive drugs in the last 3 months before the screening visit
6. Exposure to systemic corticosteroid treatment in the last 14 days before the screening visit
7. Infection(s) requiring treatment with systemic antibiotics/antivirals/antifungals within 30 days prior to the biosampling
8. Clinically detectable active infection (e.g. respiratory or gastro-intestinal)
9. Not deeming competent to make decisions regarding their own well-being due to advanced cognitive impairment or severe psychiatric disease

**Date of first enrolment**

01/05/2024

**Date of final enrolment**

30/04/2025

## **Locations**

**Countries of recruitment**

Belgium

**Study participating centre**

**Ramen en Poel**

Poel 14

Ghent

Belgium

9000

**Study participating centre**

**Kanunnik Triest**

Kloosterstraat 33

Melle

Belgium

9090

## **Sponsor information**

**Organisation**

Ghent University Hospital

**ROR**

<https://ror.org/00xmkp704>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Universitair Ziekenhuis Gent

### **Alternative Name(s)**

Ghent University Hospital, UZ Gent

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Universities (academic only)

### **Location**

Belgium

### **Funder Name**

Fonds Wetenschappelijk Onderzoek

### **Alternative Name(s)**

Research Foundation Flanders, Flemish Research Foundation, Research Foundation – Flanders, Fonds voor Wetenschappelijk Onderzoek - Vlaanderen, The FWO, Het FWO, FWO

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

### **Location**

Belgium

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a 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?
<a href="#">Protocol article</a>		01/11/2024	22/11/2024	Yes	No