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Understanding the connection between saliva and muscle loss in older adults

Submission date
21/09/2024

Recruitment status
No longer recruiting

Registration date
04/10/2024

Overall study status
Ongoing

Last Edited
22/11/2024

Condition category
Musculoskeletal Diseases

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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, 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?
Protocol article		01/11/2024	22/11/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes