Salivary Biomarkers for Non-Invasive Screening of Obesity-Related Health Conditions.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON57459

Source
ToetsingOnline

Brief title
Saliva as an easy method to detect diseases

Condition

- Diabetic complications

Synonym
Inflammation; Metabolic disorders

Research involving
Human

Sponsors and support

Primary sponsor: Onderzoekscentrum Gezond en Duurzaam Leven, Hogeschool Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Health Holland

Intervention

Keyword: Biomarkers, Metabolic syndrome, Obesity, Saliva

Outcome measures

Primary outcome

The primary endpoints of this study are the diagnostic value of salivary biomarkers, expressed as sensitivity and specificity and summarized by the area under the receiver operating characteristic curve (AUROC), to evaluate their ability in identifying metabolic dysregulations associated with obesity.

Secondary outcome

Secondary endpoints include investigating the association between clinical characteristics (e.g., obesity severity, comorbidities, medication use), demographic factors (e.g., age, gender, ethnicity) on the levels, sensitivity, and specificity of salivary biomarkers. Additionally, proteomic technologies using Olink will be used to further uncover the salivary proteomic profile of obese individuals. This approach aims to identify novel biomarkers beyond those highlighted in existing literature, offering new insights into the pathology of obesity for future studies.

Study description

Background summary

Obesity, characterized by an abnormal accumulation of body fat and chronic inflammations, leading to significant health risks including: type 2 diabetes, cardiovascular disease, liver disease, periodontitis and certain cancers. Despite these significant health risks, individuals with obesity often seek medical help after symptoms of related complications become apparent, leading to missed opportunities for early intervention.

Biomarkers, quantifiable biological indicators, are able to identify obesity-related metabolic dysregulations before symptoms appear, enabling earlier prevention and intervention. While blood is the gold standard for biomarker analysis, saliva*s non-invasive nature makes it an attractive alternative. The clinical application of salivary biomarkers however, remains limited due to the lack of comprehensive evaluation of their diagnostic value, a critical step for ensuring their sensitivity, specificity, and utility in clinical practice.

For saliva to be recognized as a reliable diagnostic tool, its accuracy must be proven to be comparable to that of blood measurements. If validated, saliva-based testing could offer a non-invasive method for health monitoring, potentially reducing or even eliminating the need for blood sampling. This would be particularly beneficial for patients requiring frequent or long-term monitoring, such as those with obesity and an elevated risk of metabolic disorders. A saliva-based diagnostic approach could not only ease the burden on patients but also enhance the accessibility of medical testing. By facilitating the early detection of metabolic disorders and enabling targeted preventive interventions, it may ultimately lead to improved health outcomes.

Study objective

The primary objective of this study is to evaluate the diagnostic value of preselected salivary biomarkers known to be significantly elevated in individuals with obesity. This includes assessing their sensitivity and specificity to ensure their reliability and utility in identifying metabolic dysregulations associated with obesity. Salivary results will be compared to blood results, which serve as the reference standard, to establish the clinical performance of saliva as a non-invasive alternative.

Study design

The study adopts a cross-sectional design comprising two distinct groups: an obese group and a non-obese group. Participants, aged 18 to 65 years, will be equally divided by gender and selected based on strict standard anthropometric criteria, including Body Mass Index (BMI), Waist Circumference (WC), Fat Mass Index (FMI) and Fat Free Mass Index (FFMI). Recruitment will be conducted in collaboration with Utrecht University of Applied Sciences, the Academic Centre for Dentistry Amsterdam, and healthcare professionals, who will approach potential participants during routine consultations and provide detailed information about the study. Saliva and blood samples will be collected.

Study burden and risks

Participation in this study poses minimal risk to both physical and mental health. However, certain aspects of the study may involve some risks or

discomfort.

Potential Risks:
- Blood Sample Collection: Blood sampling will be performed by a trained professional. Possible side effects include mild pain at the puncture site, minor bruising, or, in rare cases, slight dizziness. These effects are typically short-lived.

- Saliva Sample Collection: Collecting saliva is a simple and painless procedure. There are no known risks or side effects associated with this method.

- Incidental Findings: If a test result suggests a potential medical condition, the study physician will contact the participant to carefully explain the findings. The participant will be advised to inform their physician for further evaluation. If preferred, and with the participant*s consent, the study physician may directly inform the physician. The participant*s consent for this is documented in the informed consent form.
Approximately one week after this discussion, the researcher will follow up with the participant to determine whether any further steps have been taken and whether additional support is needed. If necessary, appropriate support will be provided.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Participants must be male or female, aged between 18 and 65 years at the time of study
participation.
2. For the obese group, participants must have a body mass index (BMI) of >= 30.0 kg/m², while
participants in the non-obese group must have a BMI within the range of 18.5-24.9 kg/m².

3. Waist circumference (WC) must meet the following requirements:
a. For the obese group: WC of >= 102 cm for men or >= 88 cm for women.
b. For the non-obese group: WC of < 102 cm for men or < 88 cm for women.

4. Participants must meet the fat mass index criteria as specified in the study protocol.

Exclusion criteria

1. Self-report or a doctor diagnosis of chronic diseases: cancer/ asthma/ COPD/ Gingivitis/ periodontitis/ Parkinson/ Type 1 diabetes/ kidney disease.
2. Chronic alcoholics
3. Currently an active smoker or residing in a household with smokers.
4. Pregnancy
5. Transgender
6. Sarcopenic obese, as defined in the study protocol.
7. History of bariatric surgery within the past 12 months.
8. Use of medications with anticholinergic effects, including antihistamines, antipsychotics, or antidepressants.

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-04-2025
Enrollment:	136
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	06-05-2025
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL88809.041.25