Dietary nitrate to preserve cardio-metabolic health during bedrest.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57333

Source
ToetsingOnline

Brief title
Nitrate-bedrest study

Condition

- Other condition

Synonym
N/A

Health condition

Niet een aandoening, maar inactiviteit en de complicaties die daarbij komen kijken.

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bed rest, Cardiometabolic health, Muscle mass, Nitrate

Outcome measures

Primary outcome

The primary endpoint is the change in leg skeletal muscle volume (measured by

MRI) before and after bedrest.

Secondary outcome

Secondary endpoints include whole-body insulin sensitivity, muscle protein

synthesis rates, mitochondrial respiration, aerobic capacity, muscle strength,

blood flow, arterial stiffness, cardiac function, and endothelial function.

Study description

Background summary

Physical inactivity due to bedrest has significant negative health impacts, including rapid muscle mass loss, loss in muscle strength, insulin resistance, and impaired cardiac function. This study aims to investigate whether dietary nitrate supplementation can mitigate these adverse cardiometabolic effects during bedrest.

Study objective

The primary objective is to evaluate the effectiveness of dietary nitrate in reducing muscle atrophy induced by bedrest. Secondary objectives include assessing its impact on insulin resistance, muscle strength, and cardiovascular function. Additionally, the study seeks to identify cellular mechanisms affecting peripheral metabolism during bedrest.

Study design

This is a single, prospective randomized study. Thirty-two healthy individuals aged 18-40 years will participate. They will be randomly assigned to receive either dietary nitrate or a placebo during a 7-day bedrest period. The study includes pre- and post-bedrest assessments.

Intervention

Participants will be randomly assigned to receive either nitrate supplements (1097 mg $NaNO_3$ in 140 mL water, providing 800 mg nitrate) or a placebo (1097 mg NaCl in 140 mL water) twice daily during bedrest.

Study burden and risks

Participants will visit the university five times over 15 consecutive days. These visits include one screening session (~1 hour), three testing days (each ~2.75, 5, 1 hours, respectively), a 7-day bedrest period, and one final test day (~2.75 hours). Procedures include metabolic rate assessments, VO_2max testing, muscle strength testing, MRI scans, blood draws, muscle biopsies, and various cardiovascular and metabolic measurements. Risks are minimal and primarily involve temporary discomfort from blood draws and biopsies, possible mild gastrointestinal distress from nitrate supplements, and potential muscle soreness from VO_2max testing. Participants will contribute to scientific knowledge that could inform future nutritional interventions to improve health and recovery in physically inactive populations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Aged between 18 and 40 y inclusive
• BMI between 18.8 and 30 kg/m2

Exclusion criteria

• Vegetarian/vegan
• Having any food allergies related to the diets that are provided (we will provide the list of food items during the screening to assess this with the volunteers)
• Smoking on a weekly basis (i.e. every week)
• Diagnosed GI tract disorders or diseases
• Diagnosed musculoskeletal disorders
• Diagnosed metabolic disorders (e.g., diabetes)
• Donated blood 2 months prior to the trial
• (Family) history of thrombosis
• Back complaints

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	29-04-2025
Enrollment:	32
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	05-03-2025
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL87477.068.24