Prevention of And Risk fActorS for chronic diseases: an Observational study in North HoLland

Published: 30-08-2023
Last updated: 22-02-2025

Primary objectives: - To examine how environmental exposures influence the prevalence, 5-year incidence and progression of cardiometabolic and chronic respiratory disease in the general population. - To determine the mediation effect of lifestyle...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON53271

Source
ToetsingOnline

Brief title
PARASOL

Condition

- Cardiac disorders, signs and symptoms NEC
- Glucose metabolism disorders (incl diabetes mellitus)
- Respiratory disorders NEC

Synonym
Cardiometabolic and chronic respiratory diseases; heart diseases, metabolic disorders and chronic lung diseases

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Deze studie is onderdeel van het P4O2 consortium: een 'public private partnership'. Het P4O2 consortium bestaat uit meer dan 20 partners, waaronder TNO, AbbVie, Aparito, Boehringer Ingelheim, Clear, Danone Nutricia Research, Fluidda, MonitAir, Ncardia, Olive Diagnostics, Ortec Logiqcare, Philips, Proefdiervrij, Quantib-U, RespiQ, Roche, Smartfish, SODAQ, en Thirona.,Health~Holland;Academic Medical Center;Stichting VUmc;Leiden University Medical Center;UMC Groningen;UMC Utrecht;Utrecht University;Maastricht University;TNO;AbbVie;Aparito;Boehringer Ingelheim;Clear;Danone Nutricia Research;Fluidda;MonitAir;Ncardia;Olive Diagnostics;Ortec Logiqcare;Philips;Proefdiervrij;Quantib-U;RespiQ;Roche;Smartfish;SODAQ;Thirona;TopMD;Lung Alliance Netherlands (LAN);the Lung Foundation Netherlands (Longfonds)

Intervention

Keyword: Glucose metabolism, Respiratory medicine, Risk factors, Type 2 diabetes

Outcome measures

Primary outcome

- The prevalence of (pre) type 2 diabetes

- The 5-year incidence rate of (pre) type 2 diabetes

- The prevalence of chronic lung diseases

- The 5-year incidence rate of chronic lung diseases

- (Change in) lung damage assessed by CT scans, only in the subgroup (n = 350)

Secondary outcome

- Lung function

- Medication use

- Blood pressure

- Respiratory complaints (including dyspnea)

- Psychological complications

- Quality of life

- Occurrence of cardiovascular disease

- All-cause and cause-specific mortality

- Fatigue

- Anthropometrics

- Dietary intake

- Physical activity

- (Change in) exhaled breath profile

- (Change in) transcriptome, genome, epigenome, metabolome and microbiome

- Residential environmental exposures, including ambient air pollution and green space

- Subjective environment and the use of green spaces

- Personal exposome measurements (only in subgroup of 350 participants)

- Willingness to participate in a combined lifestyle intervention (only in subgroup of 350 participants)

- Reasons for non-participation in the CooL program (only in participants of the subgroup fulfilling the CooL eligibility criteria) and evaluation of the experiences of participation in the CooL program

Study description

Background summary

Both the development of cardiometabolic and chronic respiratory diseases are influenced by modifiable risk factors, such as smoking, poor dietary quality and/or a lack of physical activity. Environmental exposures such as air pollution have also been shown to be risk factors for the development of both cardiometabolic and respiratory diseases. However, improved characterization of how environmental exposures interact with lifestyle factors is needed in order

to better stratify persons into appropriate risk and treatment categories. Additionally, the effect of combined lifestyle interventions on respiratory parameters need to be investigated. Because of the shared risk factors in the development of cardiometabolic and chronic respiratory conditions, this study aims to examine environmental risk factors for both cardiometabolic and chronic respiratory diseases in the general population. The results of this study will contribute to the development of innovative strategies for the prevention of chronic diseases.

Study objective

Primary objectives:
- To examine how environmental exposures influence the prevalence, 5-year incidence and progression of cardiometabolic and chronic respiratory disease in the general population.
- To determine the mediation effect of lifestyle factors and *omics profiles (i.e., biological mechanisms) in the associations between environmental exposures and the development and progression of cardiometabolic and chronic respiratory disease.
- To detect biomarkers and treatable targets for early lung damage and cardiometabolic diseases.

Study design

Prospective longitudinal observational cohort study.

Study burden and risks

All 3000 participants will be invited for two study visits that will take approximately four hours: 1) at baseline; 2) after five years of follow-up. Before the start of these study visits, participants will collect urine and faeces at home. The following measurements will be performed during the study visits: anthropometry, blood pressure, lung function, exhaled breath, nasal sampling, questionnaires, collection of fasting blood samples, and an Oral Glucose Tolerance Test. After both study visits, participants will complete the questionnaires at home, they will wear an accelerometer for seven days and track their nutritional intake through an app on their mobile phone for a maximum of 12 days. They will also have the opportunity to take a food intolerance test at baseline. Finally, participants will be requested to fill out electronic questionnaires once a year at home between the baseline study visit and study visit at t = 5 years.

We will perform additional measurements in a subgroup of 350 participants. These measurements (specifically the CT scans and personal exposome measurements) are invasive and expensive, and will therefore only be performed in a clearly defined, specific subgroup of the PARASOL study. This subgroup

will be invited for an extra study visit both at baseline and after five years of follow-up, during which a CT scan of the chest will be performed. Moreover, personal exposome measurements will be performed in these 350 participants, which will require six short home visits at baseline and t = 5 years. In addition to the study visit after five years of follow-up, the subgroup will also be invited for a study visit after one year, during which the following measurements will be performed: anthropometry, blood pressure, lung function, exhaled breath, nasal sampling, questionnaires, and collection of fasting blood samples (i.e., no CT scan will be performed at t = 1 year). After this study visit at t = 1 year, participants will again wear an accelerometer for seven days and track their nutritional intake through an app on their mobile phone. Finally, participants of the subgroup who have an indication for referral to a combined lifestyle intervention reimbursed by basic insurance (obesity, or overweight with a cardiometabolic risk factor) will be informed about the opportunity to participate in the Coaching on Lifestyle (CooL) program.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- Aged 30-55 years;
- Residing in (the vicinity of) Amsterdam or Hoorn;
- Able to provide written informed consent;
- Understanding of the Dutch language.

Exclusion criteria

- Unable to give written informed consent;
- Serious mental impairment, i.e., preventing to understand the study protocol/aim.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-03-2024
Enrollment:	3000
Type:	Actual

Ethics review

Approved WMO

Date:	30-08-2023

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL84012.018.23