hiPSC from Doetinchem Cohort Study round 8 2024-2028

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

Summary

ID

NL-OMON57454

Source
ToetsingOnline

Brief title
hiPSC from Doetinchem Cohort Study

Condition

- Other condition

Synonym
health and disease

Health condition

gezondheid en ziekten t.b.v. de volksgezondheid

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: RIVM;als onderdeel van het ministerie van VWS.

Intervention

Keyword: Disease, Health, Stemcells

Outcome measures

Primary outcome

- Ability to generate hiPSCs and differentiated derivative cells from healthy

somatic cells

- Ability to generate mutated cell lines using gene-editing

- Ability to study disease phenotype in mutated cell lines and compare it to

the control iso-genic cell lines

Secondary outcome

n.a.

Study description

Background summary

Mechanistic and causality studies are essential to validate epidemiologic associations or suspected health effects of environmental exposures. Human induced Pluripotent Stem Cells (hiPSCs) can be modelled in vitro and differentiated into different cell types of the human body, allowing mechanistic and causal studies in relevant target tissues. The genotyped participants of the Doetinchem Cohort Study with their characterized life courses (up to 35 years during their adult life) are an excellent starting point to invite a genetic diverse set of participants to contribute to a hiPSC-resource for scientific research regarding health and disease.

Study objective

The objective is to initiate a hiPSC-resource from 10 genotyped participants of the Doetinchem Cohort Study, with a characterized life course history of up to 35 years during their adult life, with the intent to deploy mechanistic and causality studies for scientific research regarding health and disease.

Study design

The Doetinchem Cohort Study is a cohort study with its origins in a random sample of Doetinchem's population. Every 5 years, participants are invited for research which consists of several questionnaires and a physical examination at the GGD in Doetinchem. This proposal is an add-on to the current ongoing measuring round 8 (METC-protocol nummer 23-169/X-A). As initiation and proof of concept of the envisioned hiPSC-resource, we will seek a total of 10 participants of round 8 willing to donate a blood sample for iPSC-generation for public health research.

Study burden and risks

Blood collection is a standard procedure, generally accepted, and also familiar to the current participants. The sensation of blood collection can be discomfortable for some participants, but the risk is considered minimal/negligible. The benefits for the participants are limited: their participation contributes to public health in general by gaining insights in health and disease mechanisms.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Belonging to the subset of 5000 genotyped Doetinchem Cohort Study participants.
- Already participated in the ongoing measurement round 8 of the Doetinchem Cohort Study.

Exclusion criteria

- Cancer patients (past or present);
- Individuals knowingly having an HIV or Hepatitis C infection.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	10

Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	28-04-2025
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	NL88899.041.25