

Night work, circadian rhythm disorders and glucose regulation, the GLU24/7 study

Submission date 11/12/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/03/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/03/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The literature suggests an association between night shift work and disturbances of the circadian rhythm causing hormonal changes and metabolic disturbances and increased risk for cardiovascular disease (CVD). No studies have yet explored whether sleep and circadian disturbances associated with consecutive night shifts have an acute impact on the ability to maintain stable blood glucose levels. Furthermore, the long-term, prospective influence of such disturbances on risk factors for developing diabetes and CVD remains unexamined, highlighting a critical gap in our understanding of the metabolic and cardiovascular implications of shift work. This study will use a comprehensive set of methods prospectively to identify the effects of shift work with night shifts on metabolic and cardiovascular health throughout 6-weeks (phase I) and perform baseline CVD-risk factor registration (phase II). The latter will be performed again after two years (phase III). The study will provide new knowledge on the association between exposure to shift work including work at night and possible metabolic disturbances and CVD risk.

Who can participate?

Workers at an industrial Pharma plant in Norway

What does the study involve?

Participants will be expected to wear an Oura Gen 3 health tracker ring, and a Continuous Glucose Monitoring (CGM) sensor, keep a food diary, and provide multiple blood samples. There will also be a clinical examination of blood pressure, resting heart rate (RHR), arterial stiffness using carotid to femoral pulse wave velocity (cfPWV), carotid intima-media thickness (cIMT), and cardiorespiratory fitness utilizing a cycle ergometer measuring maximal oxygen uptake (VO₂max)

What are the possible benefits and risks of participating?

Participants will get a thorough medical examination two years apart to check their health development.

There are no significant risks of participating.

Where is the study run from?

STAMI (National Institute of Occupational Health), Norway

When is the study starting and how long is it expected to run for?

September 2024 to June 2029

Who is funding the study?

1. STAMI
2. Borregaard Research Fund

Who is the main contact?

Dr Fred Haugen, fred.haugen@stami.no

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

24/00103

Study information

Scientific Title

Glucometabolic health and cardiovascular risk factors in night shift workers - a protocol for a 2-year longitudinal study in an industrial setting

Acronym

GLU24/7

Study objectives

Night shift work is associated with acute blood glucose variability with implications for long-term cardio-metabolic health

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 04/09/2024, REK sor-ost B (Postboks 1130, Blindern, Oslo, 0318, Norway; +4722855240; rek-sorost@medisin.uio.no), ref: 745702

Study design

Two-year longitudinal observational study

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Development of cardio-metabolic symptoms in night shift workers

Interventions

During a 6-week baseline period, sleep and physical activity will be monitored using actimetry (Gen 3 health tracker ring, OURA). Continuous glucose monitoring (Freestyle Libre Pro iQ-system, Abbott) and food diary will be performed for two weeks among all participants. Circadian rhythm markers (monocyte mRNA expression) will be analyzed at two timepoints. At the end of the 6 weeks, CVD-risk factors registration includes cardiometabolic blood parameters, markers of inflammation, and lipid profile. In this part of the study, blood pressure will also be measured, resting heart rate (RHR), arterial stiffness using carotid to femoral pulse wave velocity (cfPWV), carotid intima-media thickness (cIMT), and cardiorespiratory fitness utilizing a cycle ergometer measuring maximal oxygen uptake (VO₂max). At a 2-year follow-up, the baseline CVD-risk factor registration will be repeated.

Intervention Type

Other

Primary outcome(s)

1. The following primary outcome variables are assessed during a 6-week baseline period:
 - 1.1. Sleep and physical activity are measured using actimetry with the Gen 3 health tracker ring (OURA)
 - 1.2. Glucose variability is measured using continuous glucose monitoring (CGM) with the Freestyle Libre Pro iQ-system (Abbott) and recorded in a food diary for two weeks.
2. Circadian rhythm is measured by analyzing monocyte mRNA expression using Gene Expression Profiling (Nanostring) at two timepoints in the shift schedule; in the morning after consecutive night shifts or before a day shift in the baseline period.

Key secondary outcome(s)

The following secondary outcome cardiovascular disease (CVD) risk factors are assessed during a 6-week baseline period and at a 2-year follow-up:

1. Cardiometabolic blood parameters measured using Luminex or ELISA

2. Markers of inflammation measured using Luminex or ELISA
3. Lipid profile measured using enzymatic assays on a Cobas 8000
4. Blood pressure and resting heart rate (RHR) measured after a 5-minute seated rest from the subject's left arm utilizing a BpTRU device
5. Arterial stiffness measured carotid to femoral pulse wave velocity (cfPWV) using SphygmoCor XCEL instrument
6. Carotid intima-media thickness (cIMT) measured using ultrasound scanning of both common carotid arteries proximal to the carotid bifurcation
7. Cardiorespiratory fitness measured using a cycle ergometer to measure maximal oxygen uptake (VO₂max)

Completion date

01/06/2029

Eligibility

Key inclusion criteria

Rotating night shift work or day shift work only

Participant type(s)

Employee

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Key exclusion criteria

Issues with blood pressure

Date of first enrolment

03/10/2024

Date of final enrolment

28/02/2025

Locations

Countries of recruitment

Norway

Study participating centre**STAMI**

Gydas vei 8

Oslo

Norway

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Sponsor information

Organisation

National Institute of Occupational Health

ROR<https://ror.org/04g3t6s80>

Funder(s)

Funder type

Research organisation

Funder Name

National Institute of Occupational Health, Norway (STAMI)

Funder Name

Borregaard Research Fund

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Fred Haugen, fred.haugen@stami.no.

The health information will be given to participants if they want it. Data will be made available for participants upon request.

IPD sharing plan summary

Available on request