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

Submission date	Recruitment status	[_] Prospectively registered
11/12/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/03/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
21/03/2025	Circulatory System	[X] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Workplace

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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. 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.

Secondary outcome measures
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)

Overall study start date
04/09/2024

Completion date
01/06/2029

Eligibility

Key inclusion criteria
Rotating night shift work or day shift work only

Participant type(s)
Employee

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex

Both

Target number of participants
60

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
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Sponsor information

Organisation
National Institute of Occupational Health

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Sponsor type
Research organisation

Website
https://www.stami.no

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

Publication and dissemination plan
Several articles are planned in peer reviewed journals

Intention to publish date
31/12/2027

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