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Health effects of shift work

Submission date 25/10/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 15/11/2018	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 03/01/2024	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol

In the present project we will use advanced, recently developed methods to identify physiological effects on the cardiovascular system. This will be done by studying, Vo2 –max, blood parameters including selected markers of systemic inflammation, blood pressure/Pulse wave velocity and resting heart rate, endothelial dysfunction through measurement of the carotid intima-media thickness (IMT). Furthermore, we will register physical activity (PA) with an accelerometer and a physical activity intervention will be performed in one group of the workers. The project will provide new knowledge on the relationship between one of the major causes of death and disability in Norway, and occupational exposures to shift work. In addition to identifying factors with a large occupational health preventive potential, the project is highly relevant in a public health perspective, related to cardiovascular effects.

Background and study aims
Shift workers are exposed to long hours at work, even at nights, which can lead to negative consequences for their health. The aim of this study is to use advanced, recently developed methods to identify the physiological effects of shift work on heart health. The results will be of interest to working life in general and for the general population.

Who can participate?
Healthy volunteers aged over 18 who work at two selected industrial plants in Norway

What does the study involve?
At one of the two industrial plants the shift workers are motivated to participate 3 times a week in physical activity of high intensity lasting for 17 minutes each time. They are motivated to continue the physical activity during the 3-year follow-up. The other industrial plant receives no intervention. Participants undergo three health surveys. The health survey is conducted at the participant's local workplace and lasts about 45 minutes. The examination consists of an interview/questionnaire regarding work history, history of heart disease or other serious illness, and use of drugs and tobacco. Participants' height and blood pressure are measured using modern equipment, a non-invasive examination of the carotid artery is performed, and weight is measured. Blood samples are taken to find out whether the participants have substances in their blood that may be signs of inflammation. Aerobic fitness is determined using a graded test on a cycle ergometer. After eight weeks the tests are repeated and this is also done after three years.

What are the possible benefits and risks of participating?
The study will provide new knowledge on the relationship between heart disease and shift work. This could provide an opportunity to prevent health problems and eventual illness and may affect the assessment of potential occupational diseases. Some may find the blood sampling unpleasant. Blood sampling is usually a procedure that does not involve any risks, but injuries (bruising under the skin) may occur. To reduce risk, only trained personnel will take the blood samples. Certain blood tests used in the project may detect disease that was unknown to the participants before, in which case they will be notified and referred for further investigation.

Where is the study run from?
National Institute of Occupational Health (STAMI) in collaboration with Ringvoll Occupational Health Services (Norway)

When is the study starting and how long is it expected to run for?
June 2018 to September 2021

Who is funding the study?
Not confirmed, to be added at a later date

Who is the main contact?
Dr Marit Skogstad

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2018/1258

Study information

Scientific Title

Physiological health effects of shift work including long working hours

Acronym
SWPH

Study objectives
This project will study longitudinally whether shift work affects cardiovascular outcomes in two different enterprises in Norway. Additionally, it will study if increased physical activity among shift workers, all with predominantly sedentary work, can have a positive influence on their cardiovascular status. Risk of cardiovascular disease is increased among shift workers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee in Oslo, 11/10/2018, ref: 2018/1258/REK sør-øst B

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular health outcomes.

Interventions
Intervention will be performed in one out of two enterprises. There the shift workers are motivated to participate 3 times a week in physical activity of high intensity only lasting for 17 minutes each time of work out. They will be motivated to continue the physical activity during the 3-year follow-up.

The control enterprise receives no intervention.

Maximal oxygen uptake, blood pressure including PWV, resting heart rate (RHR) and blood samples (glycosylated hemoglobin, lipids and C-reactive protein) will be obtained at baseline and after eight weeks and finally after 3 years. IMT will be performed at baseline and final follow-up.

Intervention Type
Behavioural

Primary outcome measure
Aerobic fitness measured continuously with a Cosmed K4b2 breath by breath metabolism analyser (Cosmed Srl, Rome, Italy) and maximal oxygen uptake will be calculated from the highest 30 s averaging interval at the conclusion of the test. Measured at baseline and after 8 weeks and 3 years.

Secondary outcome measures
Measured at baseline and after 8 weeks and after 3 years (CIMT performed at baseline and final follow-up):
1. Blood pressure and resting heart rate (RHR) are measured on the left arm after five minutes of rest. The measurements are taken three times in intervals of one minute. The average of the last two measurements of both the systolic (sBP) and the diastolic pressure (dBP) will be used in the statistical analysis. Blood pressure and RHR will be measured with BpTRU® (Bp TRU medical devices, Coquitlam, Canada) on both occasions. For a more advanced registration of BP a Sphygmocor XCEL® (Sydney, Australia) devise will be used. All tests will performed using the same device and by the same researchers at the same time of the day both at baseline registration and at follow-ups.
2. Carotid intima-media thickness measured using carotid artery B-mode ultrasound imaging, Vivid iq ®. The participants are investigated about 5-10 minutes the day before the work shift, then again after the shift period and finally at the final follow-up 2-3 years afterwards. The standardized method includes measurement of mean carotid IMT of the common carotid artery (CCA) on the far wall of the CCA at least 5 mm below its end including averaged values IMT-values from both the left and right side.
3. Glycosylated hemoglobin (HbA1c) was collected in EDTA blood. Serum for investigation of lipids (cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL) and C-reactive protein (CRP) was collected on gel tubes and then centrifuged 35 x 1000 rpm for 15 minutes within 60 minutes after the blood had been drawn from a vein. The tubes were sent by mail to the Department of Medical Biochemistry Oslo University Hospital and analyzed within 24 hours. HbA1c EDTA blood was analyzed with a Tosoh G7 HPLC analyser (Tosoh Bioscience, Inc. San Francisco, CA, USA) which use high performance liquid chromatography as the separation principle.
4. Cholesterol, LDL and HDL in serum analyzed by enzymatic colorimetric method in the Cobas 8000
5. CRP in serum quantified by particle enhanced immunoturbidimetric method on Cobas 8000 (Cobas 8000 Modular Analyzer Roche Diagnostics, www.roche.com)

Overall study start date
15/06/2018

Completion date
30/09/2021

Eligibility

Key inclusion criteria
Healthy volunteers in the two enterprises

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
Some disorders will disqualify for participation in the study, such as a serious heart condition e.g. blood pressure more than 180/110 and cancer

Date of first enrolment
01/11/2018

Date of final enrolment
15/12/2018

Locations

Countries of recruitment
Norway

Study participating centre
NIOH
Box 5330 Majorstuen
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Sponsor information

Organisation
National Institute of Occupational Health

Sponsor details
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Sponsor type

Not defined

ROR
https://ror.org/04g3t6s80

Funder(s)

Funder type
Other

Funder Name
Not confirmed, to be added at a later date

Results and Publications

Publication and dissemination plan
1. Oral feedback to the participants in the study
2. The results are presented on Intranet in the company
3. The results will be presented in national and international scientific meetings
4. Publication in national journals and international peer-reviewed journals in 2019-21

If possible the trialists will provide additional documents such as statistical analysis upon publication. The protocol is not available online.

Intention to publish date
15/12/2019

Individual participant data (IPD) sharing plan
Data collected are person sensitive and are sampled from very specific plants with a limited number of participants. There is therefore a risk of identification if data on an individual level are made available. Physical documents are held in a locked room where only the project leader has access. Digital data are kept in an internal data system with two-step verification specially designed for this purpose. This area is not connected to the internet and only selected members of the research group will have access to these data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/01/2020	18/10/2022	Yes	No
Results article		12/02/2019	18/10/2022	Yes	No
Results article		02/06/2020	18/10/2022	Yes	No
Results article		10/02/2020	18/10/2022	Yes	No
Results article		12/06/2022	18/10/2022	Yes	No

Results article	3-Year Follow-Up Study	01/04/2023	03/01/2024	Yes	No
Results article	4-Year Follow-Up Study	06/02/2023	03/01/2024	Yes	No