Are AGEs, as a predictor of increased risk for cardiometabolic syndrome, increased in shift workers?

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON38945

Source
ToetsingOnline

Brief title
AGEs in Shift Work

Condition

- Diabetic complications
- Glucose metabolism disorders (incl diabetes mellitus)
- Vascular disorders NEC

Synonym
diabetic cardiovascular complications

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Advanced Glycation End products, Health, Shift work

Outcome measures

Primary outcome

Average amount of skin AGEs in shift workers and non-shift workers matched by age.

Secondary outcome

Exploring correlations, in the shift work and the control groups, between the amount of AGEs and factors that are known from the literature to play a role in shift workers: 1) age, 2) number of years working (on shifts), 3) social jetlag (Wittmann et al. 2006; Roenneberg et al. 2012), 4) eating habits (e.g. % fatty food, % sugars and timing), and 5) quality/duration of sleep. A model to assess the individual contribution of each factor on top of the contribution of being shift worker will also be explored.

Study description

Background summary

In industrialized countries, about 15-30% of the working population is involved in some kind of permanent night and rotating shift work or in intercontinental travel across several time zones. In the Netherlands around 20% of the total work force is delivered outside normal office hours. That means that many people work and eat in the evening or at night, and must sleep during daytime. Living against our biological clock can lead to a decrement of health. As a matter of fact, shift work has been associated with a number of health problems including diabetes, cardiovascular disease, impaired glucose and lipid metabolism, gastrointestinal discomfort, such as stomach-ache or diarrhea, reproductive difficulties, and breast cancer. Besides the direct effect of the

abnormal timing of food intake, shift workers eat during their active phase at night with a negative effect on blood glucose and insulin levels, it is reported that shift workers often choose specific unhealthy food items (fat and sugar) at night. This could be an important factor when looking at the increased risk for diabetes and cardiovascular disease. Diabetes and cardiovascular disease are typica medical problems related to high caloric and fat intake. This *unhealthy food choice*in combination with the fact that food is consumed at a non-optimal circadian phase explains the higher risk of shift workers for cardiometabolic syndrome.
Early screening of individuals at increased risk of cardiometabolic syndrome is critical for early treatment and/or for taking countermeasures. An indication for average blood glucose levels (glycometabloic stress) over lifetime can be obtained by measuring Advanced Glycation End products. AGEs are easily measured by means of skin autofluorescence. This technique, widely established, allows for a non-invasive measurement that has been shown to be a strong predictor of cardiovascular mortality in, for instance, diabetic patients.
Given the strong association between shift workers and cardiometabolic impairment we hypothesize that shift workers will show an increment of skin AGEs as compared to non-shift workers. If our hypothesis is proven to be valid, skin autofluorescence may, thus, be a break through non-invasive methodology to assist populations at risk, such as shift workers.

Study objective

The aim of this study is to investigate skin AGEs, as a predictor of increased risk for cardiometabolic syndrome, in a shift work population as compared to non-shift workers to assess its potential as an early assessment of the actual risk for cardiometabolic syndrome in shift work populations.

Study design

The study is an observational study, consisting of two groups. Namely a group of shift workers, and a group of non-shift workers matched by age.

Study burden and risks

No risks are associated to this study. Participation will take about 20 minutes of the subjects* time and this will include reading of the information, signing of the informed consent, completion of a general questionnaire and the measurement of skin AGEs.

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

All shift workers (male and female) who have worked on irregular schedules for at least 3 years and that have to work on average for at least 5 nights per month (at least 3 hours between midnight and 6 a.m.), will participate in this study.
Matched by age, non-shift workers will serve as a control group.

Exclusion criteria

Exclusion criteria for the shift work group is working in irregular shifts for less than 3 years, or less than 5 nights per month. Exclusion criteria for the non-shift workers group is when a person is working in irregular shifts or has been working in night shift work but not anymore at the time of the study. For both groups, people below 18 years of age are excluded.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2013
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	21-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL42910.042.12