Skin autofluorescence and regular physical activity in health and disease

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Primary objective is to assess the association between SAF and physical activity in well trained and in untrained people, and in people who have a previous cardiovascular disease. Secondary objective is, to assess if an association exists between...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON46053

Source
ToetsingOnline

Brief title
SAF-PA

Condition

- Heart failures

Synonym
Acute Coronary Syndrome, Heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Provinciale Staten;Samenwerking Noord Nederland;IAG4 project

Intervention

Keyword: AGE, Cardiovascular disease, Physical activity, SAF

Outcome measures

Primary outcome

Primary parameter is SAF.

Secondary outcome

Secondary study parameters are the frequency (times per week) and duration

(minutes per session) of physical activity, the structure and function of the

Achilles tendons, and vascular compliance.

Study description

Background summary

AGEs (Advanced Glycation Endproducts) accumulate in the skin while ageing, this is accelerated by glycemic and oxidative stress. One can easily measure the accumulation of AGEs by using skin autofluorescence (SAF). SAF is an independent predictor of (new) cardiovascular diseases (CVD) in diabetes, renal failure and existing CVD and it is related to other ageing processes. Regular moderate physical activity has a beneficial influence on state of health in the adult population. At the same time, physical activity can improve the prognosis (and survival) in patients with chronic diseases, such as diabetes, or CVD. On the other hand, extreme physical activity can cause injuries, overtraining and is correlated with an increased mortality risk.
Animal studies show that regular moderate physical activity has a beneficial influence on AGE accumulation and formation. Moreover, research in humans also provides evidence for this beneficial influence. On the other hand, increased AGE accumulation is related to an increased risk of injuries to the vascular system, tendons and bone. In this project we try to examine the role of SAF in this two sided effect of physical activity. Therefore, the hypothesis is that regular moderate physical activity lowers, and extreme physical activity increases AGE levels (measured by using SAF). Furthermore, we expect that SAF will be related to tendon and vascular compliance characteristics measured at baseline.

Study objective

Primary objective is to assess the association between SAF and physical activity in well trained and in untrained people, and in people who have a previous cardiovascular disease. Secondary objective is, to assess if an association exists between SAF and tendon- and vascular characteristics.

Study design

Cohort and intervention study, consisting of two different sub studies:
A: Investigate the effect of performing one single bout of maximal exercise on SAF in well trained and untrained people, stratified for age/gender.
B: Assess the change of SAF during a 12 week training program, stratified for age/gender.

Intervention

In part B effects of an 12 week training program on SAF will be examined; participants of groups 1, 2 and 3 will follow their regular training or rehabilitation program and matches. Measurements will be conducted after 0, 6 and 12 weeks, participants in group 3 will be measured again after one year. During these 12 weeks the participants will fill in a diary to keep track of the training sessions and matches. The control group will not follow a training program, however they do have to fill in the diary to keep track of their activities.

Study burden and risks

All performed measurements are non-invasive and therefore only minor risks are associated with participation. The use of SAF as measure for accumulation of AGEs in (longlived) skin/dermis measured with the AGE reader is widely accepted. AGE reader measurements, UTC (Ultrasound Tissue Characterization) imaging and PWV (Pulse Wave Velocity) measurements are non-invasive and the ultrasound waves of UTC imaging are not harmful for the subject. When unexpected findings are found within the measurements, the participant and (with his/her consent) the general practitioner will be informed. The risk of injuries during following the training program will not be higher than normal, because people in the study will follow their regular training program. The risk of complications in the maximal exercise test within this population (beforehand screened on risk factors) is small. To monitor the training program, people have to fill in a diary and give a Rate of Perceived Exertion (RPE) score to every training session and match. Furthermore, they have to fill in a SQUASH questionnaire about physical activity. Considering the above, we think that the burden for participants is considered acceptable and as much diminished as possible. The benefit for the participant is to get more insight into their exercise capacity, the structure and function of the Achilles tendons and vascular compliance and SAF will give an indication about the risk

for a cardiovascular disease or diabetes.

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

- written informed consent for study participation
- 18 yearsor older;For the different groups there will be specific inclusion criteria next to the criteria mentioned above. The competitive athletes and regularly training people have to fill in the PAR-Q questionnaire. They can only participate if they answer no to all questions.
;Competitive athletes:
- Training for more than 10 hours a week
- Performing an axial sport (involvement of components of jumping and running);regularly trained people
- Performing physical activity on a regular basis (regular is at least once a week for more than

60 min).
Control group
- Sedentary healthy people, performing physical activity that characterize sedentary behavior (1,0 - 1,5 MET (Metabolic Equivalent of Task)).;People who had a cardiovascular event and are going to follow a rehabilitation program
- People participating in a rehabilitation program in Beatrixoord

Exclusion criteria

- people not able or willing to sign informed consent
- tattoo on the lower part of the arm
- dark skin
- diabetes
- renal failure, eGFR<60
- known auto immune disease
- recent infection (<3 months) serious enough to result in hospitalisation

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2017
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO

Date:	07-12-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-11-2017
Application type:	Amendment
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	NL58133.042.16