# VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Ultrasound baseline

SND-ID: 2020-204-6.

# Withdrawn

This version has been withdrawn and the data are no longer available from SND's research data catalogue. Please note that there may be a newer version available.

Withdrawal due to update of SND's metadata profile. Metadata is now included in <u>https://snd.se/en/catalogue/dataset/2020-204-1/1</u>. No DOI has been generated by SND for the dataset.

### **Alternative title**

VIPVIZA

## Creator/Principal investigator(s)

Ulf Näslund - Umeå University, Public Health and Clinical Medicine Christer Grönlund - Umeå University, Department of Radiation Sciences Per Wester - Umeå University, Public Health and Clinical medicine Umeå University, Department of Public Health and Clinical Medicine

### **Research principal**

Umeå University - Department of Public Health and Clinical Medicine

### Description

The aim of the project is to develop better methods for prevention of cardiovascular diseases (CVD). It is based on the hypothesis that image-based information on subclinical atherosclerosis (i) increases the precision in the assessment of risk of CVD, (ii) improves communication and understanding of the risk, and as a consequence (iii) the motivation for and adherence to evidence-based pharmacological treatment and lifestyle modification will increase. In addition to conventional risk factor assessment and CVD prevention within the framework of Västerbotten Intervention Program.

3500 healthy participants with low/moderate risk of CVD underwent ultrasound examination of the carotid arteries and were randomized to two groups. In the intervention group, the participants and their doctors received pictorial and graphic information in color about the participant's subclinical atherosclerosis. No information about the ultrasound results was given to the control group. Follow-up after 1, 3 and 6.5 years includes sampling regarding clinical risk factors, blood for biomarker analyses, extensive questionnaires and interviews.

At 3 and 6.5 years the ultrasound examination was repeated and all participants and their doctors were informed about the results. The database also includes register data regarding prescriptions of

preventive medication, exposure data for air pollutants, data from health examinations within the VIP 10 and 20 years before VIPVIZA, and for men conscription data.

After 10 years, registry data on endpoints, CVD morbidity and mortality will be collected.

Access to VIPVIZA's data portal and research data from VIPVIZA is possible in collaboration with researchers within the VIPVIZA project. For further information, contact PI Ulf Näslund <u>ulf.naslund@umu.se</u>

Carotid ultrasound examination with Intima Media Thickness (IMT) measured in several insonation angles according to a standardized protocol and detection of plaques, as well as information to the intervention group regarding vascular age and presence of plaques

## Data contains personal data

Yes

Sensitive personal data

Yes

**Type of personal data** Medical data at individual level

Code key exists Yes

Language English

Unit of analysis

Individual/Patient

# Population

Healthy subjects aged 40-60 years at low/moderate risk of cardiovascular disease

Study design Randomised controlled trial (RCT)

# **Description of study design**

Pagmatic open-label, randomised controlled trial with masked evaluators (PROBE)

# Sampling procedure

### <u>Other</u>

Subjects having at least one cardiovascular risk factor at the occasion of participation in the Västerbotten INtervention Programme: 1) age 40 years and a first-degree relative with a history oc cardiovascular disease at an age younger than 60 years, abdominal obesity, hypertension, diabetes, LDL-cholesterol >= 4.5 mmol/l, smoking. 3) Age 60 years.

Exclusion criterion: More than 50% narrowing of the lumen of carotid areteries

# Time period(s) investigated

2013-04-29 - Ongoing

## Biobank is connected to the study

Yes

## Variables

39

## Number of individuals/objects

3532

## Data format / data structure

Numeric

## Data collection 1

- Mode of collection: Physical measurements and tests
- Time period(s) for data collection: 2013-04-27 2016-06-07
- Instrument: CardioHealth Station, Panasonic Healthcare Corporation of North America, Newark, NJ, USA - A portable ultrasound system with a linear 7MHz transducer, Ultrasound 2D, B-mode settings including depth, gain and focus point were optimized for each participant manually by the sonographer. CardioHealth Station, Panasonic Healthcare Corporation of North America, Newark, NJ, USA
- Source of the data: Research data

# **Geographic spread**

Geographic location: <u>Västerbotten County</u> Geographic description: Region Västerbotten

### Highest geographic unit

Region

# **Responsible department/unit**

Department of Public Health and Clinical Medicine

# Contributor(s)

Wolfgang Lohr - Umeå University, Department of Epidemiology and Global HEalth

# Funding 1

- Funding agency: Region Västerbotten
- Funding agency's reference number: ALFVLL-298001, ALFVLL-643391

# Funding 2

- Funding agency: The Swedish Research Council
- Funding agency's reference number: Dnr 521-2013-2708, 2016-01891, 2017-02246

# Funding 3

• Funding agency: The Swedish Insurance Society

# Funding 4

- Funding agency: Visare Norr (the four Northern Regions)
- Funding agency's reference number: 465621, 561591, 741711, 931135

## **Funding 5**

• Funding agency: The Heart Foundation in Northern Sweden

### **Funding 6**

• Funding agency: Carl Bennet Ltd, Sweden

### Funding 7

- Funding agency: Swedish Society of Medicine
- Funding agency's reference number: 405351, 503111

## Funding 8

• Funding agency: SKANDIA Risk & Health

## **Funding 9**

- Funding agency: The Heart and Lung Foundation
- Funding agency's reference number: Dnr 20150369, 20170481)

### **Ethics Review**

Swedish Ethical Review Authority - Ref. Dnr 2011-441-31M. Amendments:Dnr 2012-463-32M, Dnr 2013-373-32M, Dnr 2016-245-32M, Dnr 2017-95-32M, Dnr 2018-182-32, Dnr 2018-482-32M, Dnr 2019-0691, Dnr Ö 23-2020/3.1

### **Research area**

Cardiac and cardiovascular systems (Standard för svensk indelning av forskningsämnen 2011)

Radiology, nuclear medicine and medical imaging (Standard för svensk indelning av forskningsämnen 2011)

Clinical laboratory medicine (Standard för svensk indelning av forskningsämnen 2011)

General practice (Standard för svensk indelning av forskningsämnen 2011)

<u>Public health, global health, social medicine and epidemiology</u> (Standard för svensk indelning av forskningsämnen 2011)

Medical biotechnology (focus on cell biology (incl. stem cell biology), molecular biology, microbiology, biochemistry or biopharmacy) (Standard för svensk indelning av forskningsämnen 2011)

Psychology (Standard för svensk indelning av forskningsämnen 2011)

### Keywords

<u>Biomedical research</u>, <u>Cardiovascular diseases</u>, <u>Primary prevention</u>, <u>Ultrasonography</u>, <u>Randomized</u> <u>controlled trial</u>, <u>Risk assessment</u>, <u>Consumer health information</u>, <u>Plaque</u>, <u>Arteriosclerosis</u>

### Publications

Bengtsson, A., Norberg, M., Ng, N., Carlberg, B., Grönlund, C., Hultdin, J., ... & Näslund, U. (2021). The beneficial effect over 3 years by pictorial information to patients and their physician about subclinical atherosclerosis and cardiovascular risk: Results from the VIPVIZA randomized clinical trial. American

Journal of Preventive Cardiology, 7, 100199. **DOI:** <u>https://doi.org/10.1016/j.ajpc.2021.100199</u>

Vanoli, D. (2017). Vascular ultrasound for the assessment of carotid atherosclerosis [PhD dissertation, Umeå University]. <u>http://urn.kb.se/resolve?urn=urn:nbn:se:umu:diva-139538</u> ISBN: 978-91-7601-748-7 URN: urn:nbn:se:umu:diva-139538

Vanoli, D., Lindqvist, P., Wiklund, U., Henein, M., & Näslund, U. (2013). Fully automated on-screen carotid intima-media thickness measurement : a screening tool for subclinical atherosclerosis. Journal of Clinical Ultrasound, 41(6), 333–339. <u>https://doi.org/10.1002/jcu.22041</u> **URN:** <u>urn:nbn:se:umu:diva-78429</u> **DOI:** <u>https://doi.org/10.1002/jcu.22041</u>

Bengtsson, A., Lindvall, K., Norberg, M., & Fhärm, E. (2021). Increased knowledge makes a difference!-general practitioners' experiences of pictorial information about subclinical atherosclerosis for primary prevention: an interview study from the VIPVIZA trial. Scandinavian Journal of Primary Health Care, 39(1), 77-84.

**DOI:** <u>https://doi.org/10.1080/02813432.2021.1882083.</u> **URN:** <u>urn:nbn:se:umu:diva-78429</u>

Vanoli, D., Wiklund, U., Lindqvist, P., Henein, M., & Näslund, U. (2014). Successful novice's training in obtaining accurate assessment of carotid IMT using an automated ultrasound system. European Heart Journal Cardiovascular Imaging, 15(6), 637–642. <u>https://doi.org/10.1093/ehjci/jet254</u> **DOI:** <u>https://doi.org/10.1093/ehjci/jet254</u> **URN:** <u>urn:nbn:se:umu:diva-91057</u>

Lindahl, B., Norberg, M., Johansson, H., Lindvall, K., Ng, N., Nordin, M., Nordin, S., Näslund, U., Persson, A., Vanoli, D., & Schulz, P. J. (2020). Health literacy is independently and inversely associated with carotid artery plaques and cardiovascular risk. European Journal of Preventive Cardiology, 27(2), 209–215. <u>https://doi.org/10.1177/2047487319882821</u> **DOI:** <u>https://doi.org/10.1177/2047487319882821</u> **URN:** <u>urn:nbn:se:umu:diva-165791</u>

Nyman, E., Vanoli, D., Näslund, U., & Grönlund, C. (2020). Inter-sonographer reproducibility of carotid ultrasound plaque detection using Mannheim consensus in subclinical atherosclerosis. Clinical Physiology and Functional Imaging, 40(1), 46–51. <u>https://doi.org/10.1111/cpf.12602</u> **DOI:** <u>https://doi.org/10.1111/cpf.12602</u> **URN:** <u>urn:nbn:se:umu:diva-165443</u>

Näslund, U., Ng, N., Lundgren, A., Fhärm, E., Grönlund, C., Johansson, H., Lindahl, B., Lindahl, B., Lindvall, K., Nilsson, S. K., Nordin, M., Nordin, S., Nyman, E., Rocklöv, J., Vanoli, D., Weinehall, L., Wennberg, P., Wester, P., & Norberg, M. (2019). Visualization of asymptomatic atherosclerotic disease for optimum cardiovascular prevention (VIPVIZA) : a pragmatic, open-label, randomised controlled trial. The Lancet, 393(10167), 133–142. <u>https://doi.org/10.1016/S0140-6736(18)32818-6</u> **DOI:** <u>https://doi.org/10.1016/S0140-6736(18)32818-6</u> **URN:** <u>urn:nbn:se:umu:diva-154318</u>

Nyman, E., Lindqvist, P., Näslund, U., & Grönlund, C. (2018). Risk Marker Variability in Subclinical Carotid Plaques Based on Ultrasound is Influenced by Cardiac Phase, Echogenicity and Size. Ultrasound in medicine & biology, 44(8), 1742–1750.

## Homepage

<u>VIPVIZA</u>

## Contact for questions about the data

Ulf Näslund ulf.naslund@umu.se

## This resource has the following relations

Is obsoleted by <u>VIPVIZA - VIsualiZation of asymptomatic Atherosclerotic disease for optimum</u> <u>cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention</u> <u>Program</u>

### Related research data in SND's catalogue

Northern Sweden Diet Database (NSDD)

**NSHDS-VIP** 

<u>VIPVIZA - VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular</u> prevention – a randomized controlled trial nested in the Västerbotten Intervention Program

<u>VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention</u> <u>– a randomized controlled trial nested in the Västerbotten Intervention Program - VIP baseline</u> (lifestyle)

VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Lifestyle 1 year

VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Clinical CVD risk factors and lifestyle habits 3 year

VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Ultrasound 3 year

<u>VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention</u> <u>– a randomized controlled trial nested in the Västerbotten Intervention Program - Psychological</u> (Problem management), baseline

VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Psychological factors and reactions to the VIPVIZA intervention (Problem management), 3 years

VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - The Swedish Prescribed Drug Register

VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - VIP Historical data 10 years before baseline

VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - VIP historical data <u>20 years before basline</u>

VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention

<u>– a randomized controlled trial nested in the Västerbotten Intervention Program - Military service</u> <u>mustering register</u>

VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Data from Statistics <u>Sweden</u>

### **Download metadata**

DataCite DDI 2.5 DDI 3.3 DCAT-AP-SE 2.0 JSON-LD PDF Citation (CSL)