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.

Alternative title

VIPVIZA

Creator/Principal investigator(s)

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Research principal

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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
ulf.naslund@umu.se

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

Other
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: [Västerbotten County](#)

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

Funding 2

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

Funding 3

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

Funding 4

- Funding agency: SKANDIA Risk & Health

Funding 5

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

Funding 6

- Funding agency: Carl Bennet Ltd, Sweden

Funding 7

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

Funding 8

- Funding agency: The Heart Foundation in Northern Sweden

Funding 9

- Funding agency: The Swedish Insurance Society

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)

Public health, global health, social medicine and epidemiology (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

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

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

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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. https://doi.org/10.1093/ehjci/jet254
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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. https://doi.org/10.1177/2047487319882821
DOI: https://doi.org/10.1177/2047487319882821
URN: urn:nbn:se:umu:diva-165791

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. https://doi.org/10.1111/cpf.12602
DOI: https://doi.org/10.1111/cpf.12602
URN: urn:nbn:se:umu:diva-165443

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. https://doi.org/10.1016/S0140-6736(18)32818-6
DOI: https://doi.org/10.1016/S0140-6736(18)32818-6
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If you have published anything based on these data, please notify us with a reference to your publication(s). If you are responsible for the catalogue entry, you can update the metadata/data description in DORIS.

Accessibility level

Access to data through an external actor
Access to data is restricted

Homepage

[VIPVIZA](#)

Contact for questions about the data

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Related research data in SND's catalogue

[Northern Sweden Diet Database (NSDD)](#)

[NSHDS-VIP](#)

[VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - VIPVIZA - Included study participants](#)

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

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[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 20 years before basline](#)

[VIPVIZA VIsualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Military service mustering register](#)

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