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

SND-ID: 2020-204-1.

Associated documentation

20240506 Overview over VIPVIZA Data.pdf *(388.06 KB)*

240522 VIPVIZA_dataset description.pdf *(243.82 KB)*

Alternative title

VIPVIZA

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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

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 – Ongoing

Biobank is connected to the study

Yes

Number of individuals/objects

3532

Data format / data structure

Numeric

Data collection 1

- Mode of collection: Registry extract and/or access to biobank sample
- Description of the mode of collection: VIP historical data 20 years before basline
- Time period(s) for data collection: 1992 – 1998

Data collection 2

- Mode of collection: Registry extract and/or access to biobank sample
- Description of the mode of collection: VIP Historical data 10 years before baseline
- Time period(s) for data collection: 2000 – 2009
- Source of the data: Registers/Records/Accounts

Data collection 3

- Mode of collection: Registry extract and/or access to biobank sample
- Description of the mode of collection: The Swedish Prescribed Drug Register
- Time period(s) for data collection: 2011-01-02 – 2020-09-30

Data collection 4

- Mode of collection: Registry extract and/or access to biobank sample
- Description of the mode of collection: VIP baseline (lifestyle)
- Time period(s) for data collection: 2012-04-11 – 2016-06-01
- Source of the data: Registers/Records/Accounts

Data collection 5

- Mode of collection: Physical measurements and tests
- Description of the mode of collection: Ultrasound baseline
- 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

Data collection 6

- Mode of collection: Self-administered questionnaire
- Description of the mode of collection: Psychological (Problem management) , baseline
- Time period(s) for data collection: 2013-04-29 – 2016-06-07
- Instrument: GSE, General Self-Efficacy Scale - Self-report measure of general self-efficacy, an individual's belief in his or her capacity to execute behaviors necessary to produce performance attainments
- Instrument: LOT-R Life Orientation Test-Revised - Self-report instrument that assesses one’s dispositional level of optimism/pessimism
- Instrument: HADS Hpiostal Anxiety and Depression Scale - Self-assessment form for anxiety (subscale HADS-anxiety, 7 questions) and depression (subscale HADS-depression, 7 questions)

- Instrument: - Self-rated risk of CVD - VAS-scale
- Instrument: Brief Health Literacy Screen (BHLS) - Three questions on self-rated health literacy according to Chew
- Instrument: Brief Cope - Self-report questionnaire designed to measure effective and ineffective ways to cope with a stressful life event
- Source of the data: Research data

Data collection 7

- Mode of collection: Self-administered questionnaire
- Description of the mode of collection: Lifestyle 1 year
- Time period(s) for data collection: 2014-05-08 – 2017-11-01
- Source of the data: Research data

Data collection 8

- Mode of collection: Biological tests
- Description of the mode of collection: Lifestyle 1 year
- Time period(s) for data collection: 2014-05-08 – 2017-11-01
- Data collector: Umeå University
- Source of the data: Research data

Data collection 9

- Mode of collection: Self-administered questionnaire
- Description of the mode of collection: Clinical CVD risk factors and lifestyle habits 3 year
- Time period(s) for data collection: 2016-01-14 – 2019-06-14

Data collection 10

- Mode of collection: Measurements and tests
- Description of the mode of collection: Clinical CVD risk factors and lifestyle habits 3 year
- Time period(s) for data collection: 2016-01-16 – 2019-06-14

Data collection 11

- Mode of collection: Physical measurements and tests
- Description of the mode of collection: Ultrasound 3 year
- Time period(s) for data collection: 2016-09-05 – 2019-05-28
- 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

Data collection 12

- Mode of collection: Self-administered questionnaire
- Description of the mode of collection: Psykologiska faktorer och reaktioner på VIPVIZA interventionen (Problemhantering), efter 3 år
- Time period(s) for data collection: 2016-09-05 – 2019-05-28
- Instrument: GSE General Self Efficacy Scale - Self-report measure of general self-efficacy, an individual's belief in his or her capacity to execute behaviors necessary to produce performance attainments

- Instrument: LOT-R Life Orientation Test - Revised - Self-report instrument that assesses one’s dispositional level of optimism/pessimism
- Instrument: Brief Cope - Self-report questionnaire designed to measure effective and ineffective ways to cope with a stressful life event
- Instrument: - Specific VIPVIZA questionnaire - Self-rated risk of CVDm Specific self-efficacy, attitudes and norms related to life style habits. To the intervention group: Emotional and cognitive reactions and impact of the intervention
- Instrument: BHLS Brief Health Literacy Screen - Three questions on self-rated health literacy, according to Chew
- Instrument: HADS Hospital Anxiety Depression Scale - Self-assessment form for anxiety (subscale HADS-anxiety, 7 questions) and depression (subscale HADS-depression, 7 questions)
- Instrument: SMBQ Shirom-Melamed Burnout Questionnaire - Questionnaire to evaluate burnout

Data collection 13

- Description of the mode of collection: Included study participants
- Time period(s) for data collection: 2017-01-19 – 2017-01-19
- Instrument: Case Report Form
- Source of the data: Research data

Data collection 14

- Mode of collection: Registry extract and/or access to biobank sample
- Description of the mode of collection: Military service mustering register
- Data collector: Riksarkivet
- Source of the data: Registers/Records/Accounts

Data collection 15

- Mode of collection: Biological tests
- Description of the mode of collection: Included study participants

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: Carl Bennet Ltd, Sweden

Funding 2

- Funding agency: The Swedish Insurance Society

Funding 3

- Funding agency: The Heart Foundation in Northern Sweden

Funding 4

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

Funding 5

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

Funding 6

- Funding agency: The Swedish Research Council
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Funding 7

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

Funding 8

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

Funding 9

- Funding agency: SKANDIA Risk & Health

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

Randomized controlled trial, Plaque, Arteriosclerosis

Publications

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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

Download metadata

DataCite

DDI 2.5

DDI 3.3

DCAT-AP-SE 2.0

JSON-LD

PDF

Citation (CSL)