

Randomized clinical trial to assess the efficacy of an intervention to reduce the cardiovascular risk by improving the information given to patients

Submission date 30/01/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/02/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/06/2021	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cardiovascular disease is a term that describes conditions that affect the heart and the blood vessels. Patients at high risk of developed cardiovascular diseases need to be followed more frequently in order to monitor their blood pressure, blood cholesterol (fatty substance in the blood), and unhealthy habits, such as tobacco, not exercising, alcohol intake and diet. It is very important to reduce their cardiovascular risk through medication and non-medication programmes in order to reduce their risk, and reduce the probability of having cardiovascular events in the near future. The aim of this study is to see if a programme of providing information about cardiovascular risks can improve the risk of developing cardiovascular disease.

Who can participate?

Adults aged 40-69 who have a high risk of developing cardiovascular disease.

What does the study involve?

Participants are allocated to one of two groups. Those in the first group are visited by a research nurse every three months, and telephone calls every month, for one year. During the visits the nurse explains the concept of cardiovascular risk, and which are the best ways to reduce it, talking about tobacco, diet, complying to medication. Those in the second group receive a visit once at the beginning of the study to register health habits and to calculate cardiovascular risk. They are then followed by their GPs as per the usual standard of care. Participants are followed up after one year to measure their blood pressure and blood cholesterol levels.

What are the possible benefits and risks of participating?

Participants may benefit from a reduction in cardiovascular risk. There are no risks associated to participating in the trial.

Where is the study run from?

EAP Sardenya - IIB Sant Pau (Spain)

When is the study starting and how long is it expected to run for?
October 2016 to December 2019

Who is funding the study?
Generalitat de Catalunya (Catalan Health Department) (Spain)

Who is the main contact?
Dr Carlos Brotons (Public)

Contact information

Type(s)
Public

Contact name
Dr Carlos Brotons

ORCID ID
<https://orcid.org/0000-0001-9388-6581>

Contact details
Sardenya Primary Health Care Center
c/ Sardenya, 466
Barcelona
Spain
08025

Additional identifiers

Protocol serial number
SLT002/16/00313

Study information

Scientific Title
Multicentre, randomised, open clinical trial to assess the efficacy of an intervention to reduce the cardiovascular risk by improving the information given to patients at high cardiovascular risk

Acronym
INFORISK study

Study objectives
An intervention addressed to patients at high cardiovascular risk based on the information about cardiovascular risk can reduce cardiovascular risk and improve control of risk factors.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Study design

Multicentre randomised controlled open clinical trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

People at high cardiovascular risk

Interventions

The intervention consists of explaining cardiovascular risk in a more comprehensive way including figures, in terms of absolute risk, relative risk and vascular age.

Randomization (1: 1 ratio) is done through an electronic system that assigns the subjects in each group (intervention or control).

Intervention arm: Cardiovascular risk estimation is explained by a research nurse in a more understandable manner, using not only absolute risk, but also relative risk as well as the vascular age, with different figures. Cardiovascular estimation is done using European SCORE as well as Regicor tool. The programme is mainly focused on changing unhealthy habits, such as tobacco, sedentarism, and diet. Compliance to medication is reinforced, and control of blood pressure and lipids are monitored, with adjustment of medication if needed. Patients are visited every three months, and two telephone calls are done between each visit to reinforce changes.

Control arm: Participants are visited once at the beginning in order to register healthy habits and risk factors, and cardiovascular risk is estimated. They are then follow by their GPs as usual care.

Participants are visited every three months to monitor changes in healthy habits, risk factors, and pharmacological treatment, and reinforce the concept of cardiovascular risk.

Patients from both arms are visited again at one year (last visit) to be assessed in terms of cardiovascular risk. Blood pressure and blood cholesterol is measured as the beginning and at the end of the study.

Intervention Type

Behavioural

Primary outcome(s)

Cardiovascular risk is measured using the SCORE system as well as REGICOR tool at baseline and at one-year, at the end of the trial

Key secondary outcome(s)

1. Physical exercise is measured using IPAQ (International Physical Activity questionnaire) at baseline and at the end of the trial
2. Diet is measured using Mediterranean Diet Score at baseline and the end of the trial

3. Tobacco measured using a specific questionnaire collecting information on number of cigarettes at baseline and at the end of the trial
4. Blood lipids are measured using blood tests at baseline and at the end of the trial
5. Blood pressure is measured using a semi-automatic digital blood pressure monitor at baseline and at the end of the trial
6. Weight is measured using a digital weighing scale at baseline and at the end of the trial
7. BMI is measured using height and weight (Kg/m²) at baseline and at the end of the trial

Completion date

31/12/2019

Eligibility

Key inclusion criteria

1. Both gender
2. 40- 69 years old
3. Fulfilling at least one of the following criteria
 - 3.1. High cardiovascular risk (SCORE \geq 5% and/or REGICOR \geq 10%)
 - 3.2. SCORE relative risk \geq 4
 - 3.3. Diabetes with proteinuria or a major risk factor (smoking, dyslipidaemia or hypertension)
4. Severe kidney chronic disease (GFR < 30 mL/min/1.73 m²)
5. Subclinical Atherosclerosis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

464

Key exclusion criteria

1. Patients with established cardiovascular disease
2. Life expectancy of less than 1 year
3. Mental disease limiting patient's self-care capability
4. Drug and/or alcohol abuse
5. Already enrolled in another clinical trial

Date of first enrolment

01/10/2016

Date of final enrolment

28/02/2018

Locations

Countries of recruitment

Spain

Study participating centre

EAP Sardenya - IIB Sant Pau

c/ Sardenya, 466

Barcelona

Spain

08025

Sponsor information

Organisation

Biomedical Research Institute Sant Pau

ROR

<https://ror.org/059n1d175>

Funder(s)

Funder type

Government

Funder Name

Generalitat de Catalunya (Catalan Health Department)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Carlos Brotons at cbrotons@eapsardenya.cat.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/03/2021	17/06/2021	Yes	No

