Cardiovascular Risk in People Older Than 55 Years and Cognitive Performance at 5 Years: an Estimation Model Based on Spanish Population

Document Date: February 12, 2019
INFORMATION FOR THE PATIENT

**Study title:** Cardiovascular Risk in People Older Than 55 Years and Cognitive Performance at 5 Years: an Estimation Model Based on Spanish Population

**Introduction**

The following information describes the study and your role as a participant. The researcher will answer any questions you may have about this form and about the study. Please read this sheet carefully and do not hesitate to ask any questions you may have about the information detailed below.

**Purpose of the study**

To determine if there is a significant association between cardiovascular risk and cognitive decline after a 5-years follow-up in the population aged 55 to 74 from the NEDICES 2 study.

**Procedure**

As a participant you will need to carry out questionnaires to evaluate your memory and your current state of health. Additional data will be collected from your medical records and in the event that no data have been recorded, your doctor could complete it, if you agree, with a physical examination. The evaluation that will be performed will be the same that was already done 5 years ago in the NEDICES 2 study.

**Requirements**

You can participate in this study if you participated in the NEDICES 2 study 5 years ago.

**Disadvantages and risks**

No additional medical interventions will be performed as part of this study. Your medical care will not be affected by your participation in this study, and will continue to be ruled by the standards of good clinical practice. The approximate time required will be 45 minutes.

**Benefits**

People with a high cardiovascular risk have a greater risk of cognitive deterioration. Their participation will help to improve the knowledge of the influence of cardiovascular risk factors on cognitive deterioration. You could benefit from it if you have poor control of cardiovascular risk factors and/or memory problems by improving the control of different cardiovascular risk factors.

2000 people are planned to participate in the study.

**Confidentiality**

For all purposes, the information collected will be treated confidentially, as set out in current the Spanish legislation (Spanish Constitution, Organic Law 15/1999, of December 13, on the protection of personal data, Law 41/2002 of November 14), basic regulatory of the autonomy of the patient and rights and obligations in terms of information and clinical documentation.

**Contact**

If you have any additional questions during the course of this study about this research or your rights as a research participant, you can contact:

Name (researcher):
Phone:

**Voluntary participation**

Your participation in this study is voluntary. If you decide not to participate in this study, it will not have any negative consequences on the medical care you receive or on your participation in future research studies.
INFORMED CONSENT

Study title:
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I ………………………………………………………………………………………………………………………………………………………………………
(Full name of the participant)

I have read the information leaflet I was given.
I have been able to ask the questions that I considered appropriate.
I have received enough information about the study.

I have spoken with…………………………………………………………………………………………………………………………………………
(Full name of the researcher)

I understand that my participation is voluntary and that the data collected will be incorporated into a computerized database without my name to evaluate the research and may be used in future studies.
According to the Organic Law 15/1999 of December 13, on the Protection of Personal Data, consent to the processing and transfer of your personal data is revocable. You can exercise the right at any time by contacting the researcher.

I understand that my participation is voluntary and that I can withdraw from the study:
• Whenever you want.
• Without giving any explanation
• Without this affecting my medical care

I freely give my consent to participate in the study.

Participant’s signature  Researcher’s signature

Date of signature of the document: …………………………………………………………………………………