Germans Trias i Pujol Hospital

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HIDDEN AURICULAR AMYLOID DEPOSITS AND AORTIC STENOSIS: CLINICAL AND PROGNOSTIC IMPLICATIONS IN AORTIC VALVE REPLACEMENT SURGERY

November 3, 2020

Informed Consent

Project description:

The study aims to find out whether deposits of amyloid (an abnormal protein that builds up in tissues) in the upper chambers of the heart are linked to worse recovery after aortic valve replacement surgery. For example, it looks at whether these deposits are related to hospital readmissions, irregular heart rhythms, or problems with kidney function after surgery.

Background (context):

Some older adults who undergo surgery to replace a narrowed heart valve (called aortic stenosis) may also have small protein deposits in their heart. These protein clumps, known as amyloid, are more often found in people with a certain condition called amyloidosis. However, in many cases, these deposits are found only in the upper chambers of the heart (called atria) and without any previous diagnosis of the disease. The meaning and health impact of these hidden amyloid deposits are still unclear.

Objectives (what the investigators want to find out):

This study aimed to understand how common these protein deposits are in people with aortic valve disease, what these deposits are made of, and how they affect recovery and health after heart surgery. To do this, various types of analysis were combined, including tissue samples, blood tests, and advanced genetic studies.

Methods (what the investigators do):

During the operation, small samples were collected from the top part of the heart and analyzed in the lab using special dyes and microscopes. Substances in blood were also measured, and health status was monitored over the following year. For some samples, advanced genetic tools were used to investigate processes at the level of individual cells.

If you authorize it, this biological material will be used exclusively for the project:
HIDDEN AURICULAR AMYLOID DEPOSITS AND AORTIC STENOSIS:
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from the Cardiac Surgery and Cardiology Departments of Hospital Germans Trias i Pujol.

The remaining samples will be stored in the IGTP (Germans Trias i Pujol Institute) Biobank. You or your family may access the stored samples when needed for health-related reasons. In any case, you have the right to access, rectify, cancel, or oppose the use of your data, and to request information about the research projects in which your samples have been used, by contacting:

Biobank File Manager for Cardiology – Hospital Germans Trias i Pujol
Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol
Ctra. de Can Ruti, Camí de les Escoles s/n, 08916 Badalona, Spain
Tel: +34 93 497 8662 Email: grupicrec@gmail.com

The samples provided may only be used for biomedical research purposes in studies approved by the Research Ethics Committee of HUGTiP and in accordance with applicable legislation. Samples will be coded for use, and associated clinical data will be protected according to regulations to ensure confidentiality. If the samples are not anonymized, only authorized personnel will have access to personal data and will guarantee confidentiality.

The donation of biological samples is voluntary and free of charge.
In some cases, genetic studies may be carried out using the provided samples, and relevant information regarding your health or your family's health may be obtained. In such cases, we will contact you using the details in your medical record. Naturally, your right not to be informed of the research results will be respected.

If you sign this consent form, you may revoke it at any time by contacting the responsible person for the cardiac surgery/cardiology data file at Hospital Germans Trias i Pujol, or your referring physician. Revoking consent will not affect the medical care you receive or may receive. Upon revocation, your samples and associated data will be destroyed. If you give your consent, your samples will be used until exhausted and will not be stored for future analyses.

Project title: **HIDDEN AURICULAR AMYLOID DEPOSITS AND AORTIC STENOSIS: CLINICAL AND PROGNOSTIC IMPLICATIONS IN AORTIC VALVE REPLACEMENT SURGERY**

I, _____, have been informed by Dr. _____, a collaborator of the above-mentioned research project, and I declare that:

I have read the Information Sheet provided to me (pages 2 and 3).

I have had the opportunity to ask questions about the study.

I have received satisfactory answers to my questions.

I have received sufficient information about the study.

I understand that my participation is voluntary.

I understand that I may withdraw at any time.

I understand that all my data will be treated confidentially.

By signing below, I give my consent to participate in this study.

Patient's signature: Investigator's signature:

Badalona, _____ of _____, 20____.

I authorize the Cardiology Biobank of Hospital Germans Trias i Pujol to use both the clinical information from my medical record and the biological material obtained from tests I have undergone or will undergo, for the purpose of conducting this research project.

Patient:

Mr./Ms. _____

ID number: _____

(Signature)

Professional providing the information:

Mr./Ms. _____

Professional license no.: _____

(Signature)

I wish to be informed of research results relevant to my health or my family's health

☐ Yes ☐ No

Badalona, _____ of _____, 20____.