DEPARTMENT OF MEDICINE - DIMED Internal Medicine 4 Chief: Prof. Gian Paolo Rossi University Medical School Via Giustiniani, 2 35128 Padova



<u>Prospective Assessment of The Prevalence of Primary Aldosteronism in Hypertensive Patients Presenting with Atrial Flutter or Fibrillation (PAPPHY Study)</u>

CONSENT FORM

Dear Sir/Madam,

Italy

You are invited to participate to a study aimed at evaluating how common primary aldosteronism is in patients presenting with atrial fibrillation.

About 11% of the patients with high blood pressure have unrecognized primary aldosteronism, a potentially curable form of high blood pressure. Patients with primary aldosteronism have an aldosterone producing adenoma in more than half of the cases. This is a benign tumor that, if early identified and surgically removed, allows the cure of high blood pressure and removal of the cause of atrial fibrillation.

This study was planned to establish how many patients with high blood pressure and atrial fibrillation have an unrecognized hyperaldosteronism. Moreover, it was aimed at identifying the patients with atrial fibrillation who have also an aldosterone producing adenoma that can be surgically removed, with cure of hypertension. Hence, by adhering to the PAPPHY study you will increase the chances to receive a more accurate diagnosis of the cause of your arterial hypertension and atrial fibrillation.

All information that will be recorded for the PAPPHY Study will be treated as confidential, managed in an anonymous manner and used only for scientific purposes.

If you accept to be enrolled in this study we will draw a blood sample for routine biochemical measurements and DNA testing, which will allow detection of the genetic characteristics of the patients with primary aldosteronism and atrial flutter.

BENEFITS FOR THE GENERAL POPULATION AND YOURSELF

The study is observational and, therefore, the diagnostic procedure will be the same that are applied to the patients not enrolled in this study. The procedure leading to the identification of the cause of the atrial fibrillation and arterial hypertension could allow cure of both atrial fibrillation and arterial hypertension, with an additional benefit for the patients participating to the study.

RISKS

The enrolment in this study does not include any risk for you because no drug will be administered and no diagnostic test will be performed in addition to those administered and/or performed in the patients not included in the study.

CONFIDENTIALITY OF DATA

All scientific information will be maintained secret and will be communicated to you only if strictly necessary to ameliorate the treatment of your disease.

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ADHESION TO THE STUDY		
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	ed by the physician Drwith by participating in this study, consent to particip	
Date	(Physician's signature	
Date	(Patient's signature)	