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Country: **Italy**

Titel of the project: **Telephone-assisted INR monitoring to reduce stroke in atrial fibrillation patients**

Project details

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Award amount: €100,000

Our objective is to realize by a telemedicine system, in which patients communicate data by telephone or web connection, a telematic surveillance of international normalized ratio of AF patients to guarantee appropriate range maintenance for stroke prevention and to perform correct patients' training to obtain an adequate INR self-management.

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia and carries a 5-fold risk of stroke. In South Italy the prevalence of AF is 0,9% in males and 1,1% in females in 35-74 years old subjects and the incidence of AF-related thrombo-embolic events, including transient ischemic attacks and stroke, arrives up to 7%. In particular, in Campania, the most populated south Italian region, AF affects about 27.000 subjects and every year about 1800 thrombo-embolic events AF-related are counted. Therefore, an adequate antithrombotic strategy, resulting in high compliance to and adequacy of anticoagulant drugs would be very relevant to reduce the burden of AF-related strokes. Primary objective is to implement a telematic surveillance system of international normalized ratio (INR) to guarantee appropriate INR range to verify whether a strategy of telephone-assisted INR control reduces the occurrence of strokes and major bleedings in AF patients compared to a conventional non-telephone assisted strategy. A network between the Division of Cardiology at Federico II University of Naples (Campania, Italy) and general healthcare practitioners operating in Campania will be created. About 500 family physicians, members of 4 medical consortia will be chosen and will instruct 10-15 patients with permanent AF, according to ESC guidelines criteria, to make use of the "Telematic INR-control system" of Federico II University. This telemedicine system permits to the cardiologists participating in the project to insert patients' INR profile on a dedicate web page (centroscompenso@unina.it) as system's administrators, allows family physicians enrolled to visualize on their computer specific patients' informations by connecting to the web site by a personal username and password and permits to the patients to communicate by telephone or web connection INR data. Patients will be randomized 1:1 to the telematic INR control system or to usual INR management. Subjects will be instructed to perform, initially every week for three months, an INR control and to weekly communicate, if in the first group, by this telematic system the INR value, that will appear on the patients' web-site page. Cardiologists will then contact the patient to explain the correct anticoagulant drug dose and reasons for doses variations. After three months, if a correct INR control is reached, the INR check will be performed every 15-20 days and then every month; alternatively a weekly control will be continued. A range of INR normality will be chosen for each patient and a value outside this range will appear as an alarm on administrators' computer even if a web connection in that moment is not present. Similarly a range of ± 2 days from the scheduled INR day control will be selected, to be advised of a missed INR check from the patients. We expect to enrol about 5000 patients to demonstrate, based on AF data registered in Campania, a 25% reduction of thrombo-embolic events in 18 months (power=80%, $\alpha=0.05$). Every three months a check of patients' enrolment will be performed to establish if more family physicians needs to be contacted and to perform analyses of the occurred adverse events.

Audience

Type

- AF Patients
- Healthcare professionals

Location

Italy, Europe