

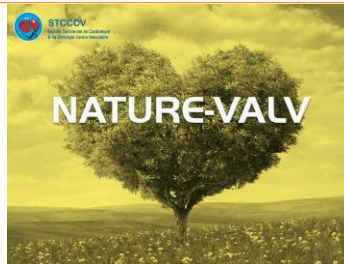
NAtional TUnisian REgistry of Valvulopathy

NCT Pending

NATURE-VALV



Tunisian Society of Cardiology and
Cardiovascular Surgery

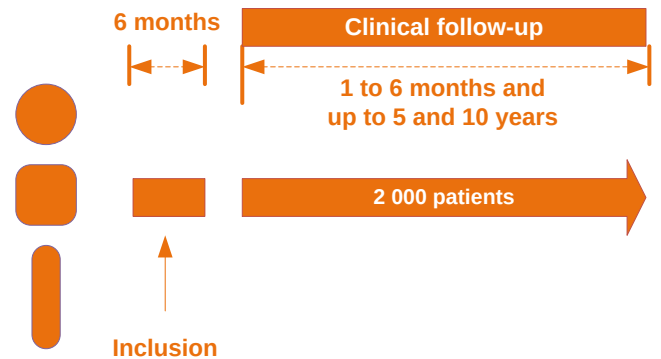


A non-interventional, national
longitudinal study of valvular
disease performed with 100
cardiologists

START DATE
September 2019

Study Summary

The NATURE-VALV study is carried out in Tunisia at cardiology consultations in hospitals and in the liberal sector. A total of 100 cardiologists participate in the selection of patients as investigators. The study is a longitudinal non-interventional registry of valvular disease. The data collected are managed by the DACIMA Clinical Suite® platform, which complies with international standards: FDA 21 CFR part 11 (Food and Drug Administration 21 Code of Federal Regulations part 11), HIPAA (Health Insurance Portability and Accountability Act), ICH (International Conference on Harmonisation). The DACIMA Clinical Suite® platform allows to track the data entered, check for inconsistencies and missing data, and schedule monitoring visits. A Steering Committee is set up to monitor patient inclusions, verify data sources, perform audit trails and prepare the statistical analysis plan for the study.



Study Objectives

- Epidemiological, clinical and therapeutic profile of valvular disease in Tunisia
- Assessment of diagnostic practices in significant valvular disease
- Assessment of indications and outcomes at 30 days of interventional and surgical procedures
- Description of education level and oral care in patients with valvular disease
- Description of therapeutic education and anticoagulation strategies in patients with valvular disease

Inclusion Criteria

- Known valvular disease (aortic bicuspidy) or multiple valvular disease with at least moderate to severe leakage, or mitral stenosis with surfing less than 2 mc^2 , or aortic stenosis with aortic maximum velocity $\geq 2.5 \text{ m / s}$.
- Or Infectious endocarditis
- Or History of percutaneous or surgical intervention on a heart valve (prosthetic valve)

Sexes Eligible for Study: All
Ages: 20 Years and older (Adult, Senior)

Exclusion Criteria

- Valvular disease with slight leakage
- Mitral stenosis with an area greater than 2 cm^2
- Aortic stenosis with a velocity of less than 2.5 m / s (when not associated with other significant valvulopathy)
- congenital cardiac condition (other than bicuspid)
- suspicions of unconfirmed infectious endocarditis