

disease – August 2022

Facts:

- There are over 33 million patients living with RHD globally, contributing to 319,000 deaths each year.
- With approximately 13 million patients, India has the largest number of people living with RHD in the world.
- Currently only onethird of RHD patients (with and without AF) are receiving digoxin treatment in India.

Project Cycle: 2021-2025

Partners:

All India Institute of Medical Sciences at New Delhi, India

Supporters: Indian Council of Medical Research

Principal Investigators

Prof G Karthikeyan, All India Institute of Medical Science, New Delhi

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Background:

- Digoxin is widely used in the medical management of patients with rheumatic heart disease (RHD) for rate control in those with Atrial Fibrillation (AF), and for treatment of heart failure (HF).
- Observational data from older patients with non-valvular AF suggest higher risk of mortality among those who received digoxin. However, patients with RHD are younger, without associated comorbidity, and it is unclear if digoxin will have similar adverse effects in these patients.

Aims:

• To determine whether the use of digoxin in symptomatic patients with RHD affects mortality, incidence of new-onset or worsening heart failure, and Quality of Life (QoL).

Methods:

- This is a 1:1 randomised, multi-centre, placebo-controlled, parallelgroup, superiority trial.
- 1,800 adult RHD patients with HF/AF will be enrolled in the study over a period of 18 months from at least 10 public referral hospitals and followed up for an average of 24 months. Vital status, new onset, or worsening HF and QoL will be recorded.

Impact:

- Quantifying the relative benefits (in terms of reduction in worsening HF) and harm (potential increase in mortality) is important as there is a lack of studies documenting digoxin's utility in this population.
- The results of this trial can be easily implemented among the population of patients who receive digoxin in clinical practice to improve health outcomes.

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