

Drug-Induced Arrhythmia Risk Evaluation (DARE) Study

BACKGROUND

- Torsades de Pointe (TdP), ventricular fibrillation (VF) and occasionally monomorphic ventricular tachycardia (VT) are well-recognised complications of cardiac and non-cardiac drug treatment.
- There is difficulty in attributing events such as presyncope, syncope and sudden death to drug therapy, given the clinical complexity of retrospective diagnosis.
- These events are not easily predictable and can appear highly idiosyncratic.
- Predisposing factors include female sex, structural cardiac disease, metabolic abnormalities, systemic and cerebrovascular disease. In addition, myocardial sodium and potassium channel mutations have been described in the inherited conditions associated with these arrhythmias: Long QT and Brugada syndromes.

STUDY AIMS

DARE STUDY

EPIDEMIOLOGICAL STUDY AIMS

- To assess the importance of this condition throughout England
- To provide data on those drugs contributing most significantly to this public health issue
- To determine patient outcome in terms of cardiac events and mortality compared to a control patient group
- To determine the relative risk of acknowledged predisposing risk factors

GENETIC STUDY AIMS

- To demonstrate that the above mentioned mutations are commoner in a population suffering pro-arrhythmia compared to a control patient group
- To determine the relative risk of genotype

CASE RECRUITMENT

- We aim to recruit patients who have suffered a proarrhythmic event over a 5-year period from physicians in England including those who are cardiologists and electrophysiologists.
- Inclusion criteria will be at least one of the following, diagnosed as secondary to therapeutic drug administration or overdose:
 - Documented TdP, VF or non-polymorphic VT
 - Exacerbation of an already existent ventricular arrhythmia
 - Severe QT prolongation (corrected QT interval ≥ 500 ms)
 - Moderate drug-induced QT prolongation (QT interval ≥ 450 ms (male) or ≥ 470 ms (female)) **and** a clinical history of syncope or presyncope
- We will simply request that you ask appropriate patients who are agreeable to participating to return a card (supplied by us) to the Drug Safety Research Unit (DSRU). This will demonstrate consent by the patient to be contacted and help to facilitate arrangements for interview by a research nurse at the patient's home.
- We will deal with NHS R&D/Trust approval issues as they arise.

BENEFITS OF THE STUDY

- We expect to further understanding of this rare but important serious adverse drug reaction. This will contribute to the safer development and prescription of drugs and improve prediction of future proarrhythmic risk for other patients and their families.

PLEASE CONTACT US FOR A DETAILED INFORMATION PACK:

dare@dsru.org

www.dsru.org

023 8040 8615