AIMS & OBJECTIVES

The present study was undertaken to stress the relevance and importance of Pharmacovigilance in the Indian context and highlight the fact that a reliable system of Pharmacovigilance is extremely essential for the rational, safe and cost-effective use of medicines. In situations that involve the use of medicines for treatment of diseases with multiple drug therapies, various medicines could interact with each other, significantly increasing the exposure to the risk of Adverse Drug Reactions (ADRs). Thus a robust Pharmacovigilance programme for post-marketing surveillance of drugs is important for monitoring the occurrence and frequency of known ADRs and detection of previously unknown adverse events. With this rationale the aims and objectives of the present study were:

Aims:

1. Development of a Pharmacovigilance Programme
2. Testing of the developed programme in Psychiatry, HIV with co-infection of Tuberculosis.

Objectives:

1. Development of a Pharmacovigilance programme which involves:
   
   A. Risk minimization through training and safe care delivery in the management of Kala-Azar
   
   B. Risk assessment
   
   C. Analysis of Pharmacovigilance data
2. To test the developed programme:

   A. By performing retrospective analysis of adverse drug reactions in HIV/AIDS and TB co infected patients on HAART (Highly Active Anti Retroviral Therapy).

   B. By conducting intensive adverse drug reaction monitoring in Psychiatry.

The present study was thus focused on first developing a Pharmacovigilance programme and demonstrating the various aspects involved. For running a successful pharmacovigilance programme, training of healthcare professionals and health workers is necessary, so the present work also focuses on development of a training module for imparting Pharmacovigilance training in the area of Visceral leishmaniasis for a new teratogenic drug Miltefosine.

Testing of the developed programme was then to be undertaken by retrospectively analyzing the ADRs in HIV and HIV/TB co infected patients, ADR reporting practices and the completeness of ADR data collected at one of the most organized department of a tertiary referral centre which is the ART (Anti Retroviral Centre). Then through a prospective study, implement a pharmacovigilance programme by taking psychiatry department of a tertiary referral centre as a prototype. Psychiatry department was selected as there are many adverse drug reactions reported to psychotropic drugs which affect the quality of life and compliance to treatment, and also not many studies are carried out in the Indian population to study the nature and type of these ADRs. Medicines for
psychiatric disorders are usually taken lifelong or for longer duration of time which was another reason for selection of this area for the present study.