

4th International Conference and Exhibition on Pharmacovigilance & Clinical Trials

August 10-12, 2015 London, UK

Breast cancer and cancer drug safety

Ashok Srivastava, Ramesh Anumolu and Pallavi Dhillon Global PharmaTek Oncology, USA

Breast cancer remained the most common cancer in women and its incidence continues to rise. Nonetheless, mortality is falling, partly as a result of earlier diagnosis through mammographic screening, improved surgical techniques and attention to margins, improved delivery of radiotherapy, and better adjuvant medical therapies. Despite these improvements, breast cancer remains the second most common cause of death from cancer in women. About one-third of newly diagnosed patients will eventually recur and/ or develop metastatic disease. One of the old cancer drugs, doxorubicin is one of the most active and versatile anticancer agents. It has an exceptionally broad spectrum of activity, and plays a leading role in the curative and palliative therapy of a diverse group of malignancies, most notably breast cancer, lymphoma, soft tissue sarcoma, various pediatric malignancies, multiple myeloma, and advanced bladder cancer. But its use is limited by cardiotoxicity. The incidence of clinically significant cardiomyopathy or congestive heart failure rises with increasing lifetime cumulative doses of doxorubicin and also the other drug given in a combination regimen that includes drugs such as cyclophosphamide or paclitaxel, as well as newer biologic therapies, including trastuzumab. The breast cancer drug's safety and pharmacovigilance will be discussed and presented at this meeting in detail along with breast cancer patient's care.

ashok@Globalpharmatek.com

Quality of clinical trials for selected priority mental and neurological disorders in sub Saharan Africa: A systematic review

Anwar Mulugeta, Girmay Medhin, Getnet Yimer and Abebaw Fekadu Addis Ababa University, Ethiopia

Background: There is a developing consensus on the effectiveness of various interventions for mental disorders in low and middle income countries, and it has been proposed that the main task that remains is to scale up these interventions. In this context we aimed to look at the quality and extent of intervention trials for selected priority mental and neurological disorders in sub-Saharan Africa.

Methods: We used Medline, AJOL and Google scholar databases. Randomized or non randomized clinical trials for the treatment of schizophrenia, depression, maternal depression, bipolar disorder and epilepsy/seizure disorders that involve pharmacotherapy, psychotherapy and physical therapy were included. Extensive list of search terms that identified locations, disorders, interventions and study types were employed. The qualities of the trials were appraised using the single component quality assessment of CONSORT-statement and the Jadad scale.

Results: From 1136 studies identified, only 34 trials that fulfilled inclusion criteria were used for quality analysis. Most studies were clinical trials of treatments for epilepsy and conducted after 2006. In terms of region, South Africa had the lion's share hosting 22 of the 34 studies. Pharmacotherapeutic interventions (71%), and conducted at a single center (53%) predominated. In terms of methodological quality in relation to the Jadad scale, 82% fulfill criteria for good methodological quality with a score of 3-5. However, the methodological quality according to the CONSORT criteria was more mixed.

Conclusions: The overall quality of clinical trials conducted in Sub-Saharan Africa is encouraging despite the limited number. However, important quality limitations remain and have not improved over time. Establishing clinical trial centers in these countries may be one approach to improve quality and quantity of trials.

anis2world@gmail.com