

Editor's Note: Journal of Clinical Trials

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Editor's Note

In clinical research, several studies use to perform on human subjects to evaluate the dependence of the disease occurrence with one or more parameters. Such studies are called 'Clinical trials', which are having great importance in medical sciences. Clinical trials mainly deals with biomedical, biochemical and behavioral tests on subjects but in some special cases commentary of care giver or parent plays crucial role in determining the actual scenario. The most crucial aspect of clinical results is its reproducibility and authenticity, which sometimes guide the fellow physician to postulate the therapeutic paradigm for a challenging issue. Pharmaceutical industries are the most dependent sector on clinical trial because, success in clinical trial only bring forward the 'Approved Drug'. Not only drug or medicine, various medical devices are also subjected to clinical trial and only successful device can be allowed to do business without any restrictions. Present 'Journal of Clinical Trials' accumulates all the relevant information on clinical research and provides a scope for communication of the articles related to clinical trials.

The Journal of Clinical Trials is aimed at presenting the latest trial designs and results. The current issue of the Journal of Clinical Trials presents some interesting trial designs and case reports. Xynos et al. [1], proposed a clinical trial protocol for verifying if oral antibiotics are sufficient to prevent surgical site infections (SSI) in the absence of mechanical bowel preparation (MBP). Makabe et al. [2], delineated the protocol used for the Asian Nurse Quality of Life Study (ANQueSt). Majda et al. [3], present a case of erythroderma associated with ribavirin and PEGylated interferon (PegINF) alpha-2a combination therapy. Ilhame et al. [4], present the case report of a 52-year-old woman presenting numerous erythematous-squamous and pruritic plaques of the trunk, which were aggravated by the progressive occurrence of diffuse bullous and erosive lesions. Albanese et al. [5], compared the femoral artery access site complications after percutaneous coronary interventions (PCI) in: (1) standard care, and (2) patients undergoing treadmill electrocardiographic (ECG) stress test within 24 h of employment of the Angioseal™ vascular closure device; the authors found that early treadmill testing can be performed without any major restrictions or complications in patients. Gus et al. [6], performed a comparative analysis of the Lens Opacity Classification System III (LOCSIII) and the Scheimpflug system in a presenile cataract population; the authors observed the Scheimpflug system to be more useful in tracking cataract development, and the LOCSIII to be useful at cataract diagnosis.

Recent evidence suggests that, mechanical bowel preparation (MBP) in conjunction with oral antibiotics significantly reduces postoperative morbidity, through prevention of anastomotic leakage and surgical site infections (SSI). Xynos et al. [1], proposed that, oral antibiotics by themselves are sufficient to prevent SSI. The authors suggest a trial design involving randomization of patients scheduled for colectomy (termed MECCLAND-C) or low anterior resection of the rectum

(termed MECCLAND-R) into two arms; Arm A: MBP only; Arm B: MBP plus oral antibiotics. All patients are to be administered intravenous antibiotics one hour prior to surgery. The primary end points to be considered are SSIs including (1) superficial wound infection, (2) deep wound infection, and (3) intra-abdominal infection. The authors suggest a randomization rate of 1:1 and the sample size of 356 for either of the Arms, as parameters for a successful MECCLAND-C or MECCLAND-R trial.

The quality of life (QoL) of hospital-based nurses is affected by job satisfaction, social support, job stress, and coping mechanisms. These relationships appear to be uniform across countries. Nonetheless, comparisons of QoL of nurses in Asia are very limited. The Asian Nurse Quality of Life Study (ANQueSt) was initiated to compare the QoL of nurses across Asia, and to identify the variables associated with the QoL. Towards this, a questionnaire based cross-sectional study was conducted on nurses from five Asian countries (Bhutan, Japan, Malaysia, Singapore, and Thailand). The inclusion criteria for the study were: (1) must belong to Asia, (2) must work at a teaching hospital, and (3) must have obtained the nursing director's agreement. In this issue, Makabe et al. [2], have delineated the protocol used for ANQueSt.

The combination of interferon Alpha with ribavirin can successfully eliminate hepatitis C virus (HCV) infection in 40–90% of patients. But, the dermatological adverse events associated with this combination therapy are fast becoming apparent. These adverse events range from eczema to autoimmune disease. Majda et al. [3], present the case report of a 73-year-old male with a history of Hepatitis C who was being treated with a combination of ribavirin and PegINF alpha-2a. A week prior to completion of his treatment, the patient complained of generalized itches associated with skin infiltrations, which was identified as erythroderma. Physical examination revealed bilateral axillary lymphadenopathies. Lab studies revealed the presence of inflammatory anemia with lymphopenia at 920 elements/IU; eosinophilia at 1700 elements/IU; and hypoalbuminemia at 30 g/L. Cutaneous biopsy revealed apoptotic bodies in the epidermis.

Bullous mycosis fungoides is a rare form of cutaneous T-cell lymphoma, which can turn aggressive with an unfavorable prognosis. Mechanism of bullous lesion formation in bullous lymphoma is poorly understood. Ilhame et al. [4], present the case report of a 52-year-old woman presenting numerous erythematous-squamous and pruritic plaques of the trunk for the past 3 years, which were later aggravated by the progressive occurrence of diffuse bullous and erosive lesions.

Albanese et al. [5], compared the femoral artery access site complications after the administration of percutaneous coronary interventions (PCI) in: (1) standard care, and (2) patients undergoing treadmill electrocardiographic (ECG) stress test within 24 h of employment of the Angioseal™ vascular closure device. This was a randomized, single-center cohort study conducted on 221 patients. Within 24 h of PCI, duplex ultrasound (DUS) of the inguinal region

was performed in both groups. The DUS was repeated immediately post the treadmill electrocardiographic (ECG) stress tests in the exercise group. Results showed that early treadmill testing can be performed without any major restrictions or complications in all patients.

Cataract, or lens opacity causes significant loss of visual acuity, and is the principal cause of blindness (48%) across the world. Senile or age-related cataract is the most common form of cataract; it usually affects the elderly. The Lens Opacity Classification System III (LOCSIII) is considered to be the gold standard test for the diagnosis of cataract. However, this method is liable to be less reproducible as it is dependent on the interpretation of the examiner. The Scheimpflug system is a non-invasive method for the early diagnosis of cataract. Compared to non-diabetic individuals, diabetics are 29 times more likely to experience blindness; it is estimated that 80% of the diabetics will manifest diabetic retinopathy to some extent within 25 years of being diagnosed. Diabetic retinopathy is often co-diagnosed along with cataract. Cataract is thought to be more prevalent in diabetics; but, there are no studies to substantiate such claims. Gus et al. [6], compared the results of LOCSIII with the Scheimpflug system in a presenile population. The results revealed that the Scheimpflug system is more useful in tracking cataract evolution as opposed to early diagnosis. LOCS III on the other hand, is less expensive method for early diagnosis of cataract.

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