Correspondences

Conducting placebo controlled randomized trials

Sir,

I read with great interest the article entitled “Vitamin D levels in Indian children with intrathoracic tuberculosis” published recently. The authors deserve credit for their effort. However, while going through the article, it was difficult to arrive at any conclusions regarding the aim/objective being fulfilled by this study. This may be because the methods described by the authors seem inadequate in handling the described design of the study. Further, the methods have not been completely outlined by the authors. A few of my concerns are highlighted here. The authors stated that the study was conducted in 266 children enrolled in a placebo controlled randomized controlled trial on micronutrient supplementation in children with intrathoracic tuberculosis. The authors further stated that all consecutive children of either sex, between 6 months to 15 yr of age, suffering from probable pulmonary and/or pleural tuberculosis were recruited in 2009-2011 from the Paediatric TB Clinic of two tertiary care centres of New Delhi.

The authors have not mentioned as to how the groups were created after random allocation and which group received the placebo. At times it appeared as if the study was part of an ongoing study and not an independent study itself. In both cases it would have benefitted the reader, if the detail of case selection and randomization was provided in the study. Placebo-controlled study is a way of testing a medical therapy in which, in addition to a group of subjects that receives the treatment to be evaluated, a separate group receives a sham placebo treatment which is specifically designed to have no real effect. Placebos are most commonly used in blinded trials, where subjects do not know whether they are receiving real or placebo treatment. Often, there is also a further “natural history” group that does not receive any treatment at all.

In most cases, the stated purpose of the placebo group is to account for the placebo effect that is, effects from treatment that do not depend on the treatment itself. As the authors have not deliberated on placebo use in the study, the placebo effect has not been demonstrated.

Sunil Kumar Raina
Department of Community Medicine
Dr R.P. Government Medical College
Tanda 176 001, Kangra, Himachal Pradesh, India
ojasrainasunil@yahoo.co.in

Reference