

Myopia prevention – what is the difference between a statistically and clinically significant benefit of different treatments.

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The results of myopia treatment trials are often presented as percentage benefits. However, for example, a 50 % benefit in spherical equivalent (SE) change between treatment and control group can be obtained from 0.1 D vs 0.2 D, or 1.0 D vs. 2.0 D changes. It is important to report at what stage of the treatment trial the difference in refraction change has occurred and what were the final refraction values. When showing graphically the SE changes in the treatment and control groups a preferable approach would be to show the changes from the baseline SE values relative to the starting age.

There is a large individual variation in the progression of myopia. The progression of myopia in two same aged myopics from same myopia can differ significantly from each other. Comparability would improve if randomization to the treatment and control groups could be carried out, for example, six months or one year before the start of the treatment intervention. In this way, the potential effects of the natural progression of myopia in study groups could be taken into account.

Before new therapies are generally introduced, a number of independent studies on the benefits, potential harms and complications of treatments should be conducted using sufficiently large number of subjects. The practical benefits of treatments should be evaluated against changes in refraction and final refraction values and potential complications.

The presentation discusses in more detail the challenges that may affect the reliability of clinical trials for myopia treatment.