## The Rationale of clinical trial

In conjunction with the growth of the child's body, the size of the eyeballs also grows. This growth is regulated by a number of external and internal mechanisms, and their disruption leads to pathological growth, excessive elongation of the axial length of the eye and the development of short-sightedness (scientifically known as myopia). The main symptom of myopia is blurred vision or blurry distance vision. Myopia is usually diagnosed in children between the ages of 5 and 7 and is irreversible. The most common way of treating childhood myopia is correction using dioptric glasses. A medicinal product called atropine is used in clinical practice to control the growth of myopia. Interim results of clinical trials show that low-doses of atropine, usually given as eye drops at bedtime, can slow the progression of myopia in children and thus prevent severe myopia. However, children treated with low doses of atropine still need glasses.

The investigational medicinal product is highly diluted atropine collyrium (eye drops) in two concentrations (0.02% and 0.04% atropine). In the control arm, a placebo collyrium will be administered. The randomization ratio was set as 2:1:1 to the 0.02% atropine, 0.04% atropine, and placebo arms. Treatment with the study medication will then be taken from the randomization for two years daily, for another 1 year the patients will be monitored as part of a washout period (without active treatment) to evaluate the rebound phenomenon. As part of the study, ophthalmologic examinations will be performed to evaluate the primary and secondary objectives of the study. Treatment safety will be monitored using records of all adverse events and treatment-related adverse events, as well as patient-rated outcomes.