Safety

During the VISION study and the second and third year extension no increased risk of systemic adverse events was identified, but patients with high risk of cardiovascular and cerebrovascular events were excluded from the clinical trials.

Most adverse events reported in the study eyes were attributed to the injection procedure.

The low risk of serious injection-related adverse events, such as endophthalmitis, traumatic cataract and retinal detachment were found to be modifiable with injection protocols changes during the study
(Table 1).

Because VEGF is involved in a wide range of physiological processes, inhibition of this factor raises many safety concerns particularly in the context of extended treatment regimens[(75-77)].

The pegaptanib sodium selectively inhibits the most biologically active isoform of VEGF (VEGF 165), and according to some authors this quality allows a theoretical advantage in terms of safety comparing to the non-selective anti-VEGF like ranibizumab and bevacizumab.

The systemic risks of non-selective VEGF inhibition have been illustrated with the use of intravenous injection of bevacizumab for the treatment of metastatic colorectal and non-small-cell lung cancer, both approved indications for this agent.

Nevertheless, the intravitreous administration of anti-VEGF agents for the treatment of exudative AMD results in much lower systemic exposures[(65)].

Although the theoretical superior safety of pegaptanip in comparison to other non-selective anti-VEGFs this has not been confirmed yet.

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