Photosensitizer Radachlorin®: Skin cancer PDT phase II clinical trials.

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Source

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Abstract

"Radachlorin"(®), also known in the EU as Bremachlorin, a composition of 3 chlorophyll a derivatives in an aqueous solution, was introduced into the Russian Pharmacopoeia. Its GMP (Good Manufacturing Practice) facility based manufacturing method was patented. Laboratory experiments and clinical phase I were performed. Protocols were designed for PDT of basal cell carcinoma of the skin to result in GCP (Good Clinical Practice)-conformed randomized phase II clinical studies. "Radachlorin"(®) solution for intravenous infusions 0.35% 10mL in the doses of 0.5-0.6 and 1.0-1.2mg/kg and a gel for topical application 0.1% 25g in the dose of 0.1g/cm(2) were photoactivated by 2.5W 662nm semiconductor laser "LAKHTA-MILON(®)" (St. Petersburg, Russia) in light doses of 200, 300 (solution), 400, 600, 800 (gel) J/cm(2). Safety study showed no side effects and a good tolerability of "Radachlorin"(®) by patients. There was no normal skin/subdermal tissue damage after both laser and sun light exposure. The main part (98%) of the drug was excreted or metabolized in the first 48h. Drug administration at a dose of 1.0-1.2mg/kg and irradiation at 3h with 662±3nm light at a dose of 300J/cm(2) (solution) and 4 PDT sessions at an interval of 1 week with 3h gel exposure, followed by 400J/cm(2) light exposure (gel) were found to be the optimal treatment regimes. Having successfully passed clinical trials, "Radachlorin"(®) achieved marketing authorization in Russia in 2009 and a conditional approval in South Korea in 2008. It is a candidate for phase III clinical trials in the EC and may be commercialized as a prospective second-generation photosensitizer.

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