primary studies - published RCT

Safety and pharmacokinetics of Roscovitine (Seliciclib) in cystic fibrosis patients chronically infected with Pseudomonas aeruginosa, a randomized, placebo-controlled study.

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Study design (if review, criteria of inclusion for studies)

Phase 2 trial study (ROSCO-CF), multicenter, double-blind, placebo-controlled, dose-ranging study

Participants

Pseudomonas aeruginosa infected adult CF patients carrying two CF causing mutations (at least one F508del-CFTR mutation) and harboring a FEV1 â‰¥40%.

Interventions

200, 400, 800 mg roscovitine, orally administered daily for 4 days/week/4 weeks

Outcome measures

Safety and effects of roscovitine; levels of inflammation, infection, spirometry, sweat chloride, pain and quality of life

Main results

Among the 34 volunteers enrolled, randomization assigned 11/8/8/7 to receive the 0 (placebo)/ 200/400/800 mg roscovitine doses, respectively. In these subjects with polypharmacy, roscovitine was relatively safe and well-tolerated, with no significant adverse effects (AEs) other than five serious AEs (SAEs) possibly related to roscovitine. Pharmacokinetics of roscovitine were rather variable among subjects. No significant efficacy, at the levels of inflammation, infection, spirometry, sweat chloride, pain and quality of life, was detected in roscovitine-treated groups compared to the placebo-treated group.

Authors' conclusions

Roscovitine was relatively safe and well-tolerated in CF patients especially at the 200 and 400 mg doses. However, there were 5 subject withdrawals due to SAEs in the roscovitine group and none in the placebo group. The lack of evidence for efficacy of roscovitine (despite encouraging cellular and animal results) may be due to high pharmacokinetics variability, short duration of treatment, and/or inappropriate dosing protocol.

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See also

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Keywords

Roscovitine; CYC202; Seliciclib; Anti-Inflammatory Agents - excl Steroids; pharmacological_intervention;