New naloxone capsule safe for opioid-induced constipation

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(HealthDay)—A new naloxone sustained release (NSR) capsule appears to be safe and efficacious for opioid-induced constipation (OIC), according to a study published online June 24 in *Pain Medicine*.

Mark Sanders, M.D., from the Norfolk and Norwich University Hospital in the United Kingdom, and colleagues examined the safety and efficacy of a new NSR capsule for treating OIC. Forty patients with OIC were randomized into four cohorts of 10 patients in a multiple ascending dose design (2.5, 5, 10, and 20 mg). Within each cohort, eight patients were randomized to active therapy and two to matching placebo.

The researchers found that the placebo group had the highest incidence of treatment emergent adverse events, with similar incidence among the

four active treatment groups. No serious adverse events occurred. For 2.5, 5, 10, and 20 mg NSR capsules taken once daily, the mean change in spontaneous bowel movements from baseline was 2.21 ($P = 0.052$), 2.37 ($P = 0.032$), 4.11 ($P = 0.0005$), and 5.19 (P

"This Phase II study has shown that using a new sustained release formulation to deliver oral naloxone to the colon allows successful treatment of OIC without comprising the desired opioid effects," the authors write.

Several authors disclosed financial ties to pharmaceutical companies, including Althean Pharma, which is co-developing NSR. The study was partially funded by SLA Pharma.

  More information: Abstract
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