Naltrexone implant improves HIV treatment outcomes compared to oral naltrexone in opiate addicted patients

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- **Aim:** HIV+ opiate users often have poor adherence to antiretroviral therapy (ART). A one-gm extended release naltrexone implant (NI) prevents relapse for ~ 3 months and improves addiction outcomes. We aimed to assess the impact of NI compared to 50 mg daily oral naltrexone (ON) on ART outcomes.

- **Methods**: 200 detoxified HIV+ opiate addicted patients starting ART in St. Petersburg, Russia were randomized 1:1 to 12 months of NI + ON placebo, or ON + NI placebo. All were offered every other week counseling. Outcomes included a primary outcome of plasma HIV RNA (LLQ=400 copies/ml) at month 12 and secondary outcomes of adherence to addiction treatment, retention in ART and ART adherence, CD4 count, opiate use, and adverse events.

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- **Results:** Baseline characteristics were similar between groups. HIV RNA suppression was more common in NI than ON [66% vs 50%; OR (95% CI) = 1.94(1.10-3.43)], Addiction treatment was more often completed in NI than ON (32% vs 17%, respectively, $p<0.05$), and retention in ART care was better in NI than ON (46% vs 32%; $p<0.05$). The proportion of taken ART tablets according to MEMS cap openings was higher in completers vs. dropouts: 73,7% (95%CI: 67.2-80.2%) vs. 64.9% (95%CI: 59.7-70.1%; F1, 198 = 4.37; P= 0.038). CD4 count increase was higher in those who continued on naltrexone, regardless of group assignment, vs. those who dropped out (CD4 change at the end of treatment compared to baseline (completers vs. drop outs, M±SD) 206.2 cells/mm3 ±201.8 vs. 67.3 cells/mm3 ±159.4, $p<0.001$). The groups did not differ in adverse events (32% for ON vs. 30% for NI, $p>0.5$?).

- **Conclusion:** NI improved HIV and addiction outcomes compared to ON in opiate addicted patients initiating ART in Russia. Extended release naltrexone may be a useful alternative to methadone or buprenorphine maintenance for opioid addicted patients on ART who do not want agonist therapy or where it is difficult to access or unavailable.