

Does timing matter for initiating HIV therapy in infants?

January 7 2020



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Starting HIV antiretroviral therapy (ART) within hours of birth has been hypothesized to have positive effects raising the possibility of remission in some children with HIV. To test the hypothesis, researchers at



Columbia Mailman School of Public Health and Columbia University Irving Medical Center designed a trial in a group of newborns with HIV who started ART within 14 days of birth. The results showed that about 75 percent of infants attained viral suppression on ART; but only 52 percent attained and sustained viral suppression on ART. The success of attaining and sustaining viral suppression was similar in the 46 infants starting ART less than two days old (51 percent) and the 27 infants starting therapy between 2 and 14 days after birth (54 percent). The findings are published online in *E-Clinical Medicine*.

"The results of our trial suggest that very early treatment in newborns may not have to mean within hours of birth," said Louise Kuhn, Ph.D., Columbia Mailman School professor of epidemiology (in the Sergievsky Center). "We learned that we must be more attune to basing decisions about how quickly to start ART on optimizing maternal adherence with treatment rather than with just focusing on speed. While we certainly do not want to introduce undue delay, starting ART within the first two weeks of life led to similar outcomes to starting within the first two days of life."

The study was designed shortly after the report of the infant in Mississippi who started antiretroviral treatment within 30 hours of birth and who was able to maintain viral suppression off treatment for over two years. This case report led to optimism that ART started within hours of birth may lead to protection of critical immune processes and smaller viral amounts, making possible remission in a sizable minority of infants treated in this way. "The outcome in Mississippi raised the tantalizing possibility that we may be able to facilitate remission in infants if we start ART very early in life," noted Kuhn.

To yield the target population for the trial, clinical protocols were established at Rahima Moosa Mother and Child Hospital (RMMCH), Johannesburg, South Africa. The analysis included 73 children who were



born between March 1, 2015 and September 30, 2017 with confirmed HIV infection and ART initiated within 14 days. The initial ART regimen consisted of nevirapine, lamivudine and zidovudine; nevirapine was replaced with lopinavir-ritonavir once the child reached 42 weeks post-menstrual age, usually about 4 weeks of age in calendar time. ART was initiated based on results of the first round of diagnostic testing and was continued throughout the study.

Of those surviving during the study, 75 percent attained viral load

Citation: Does timing matter for initiating HIV therapy in infants? (2020, January 7) retrieved 3 May 2024 from https://medicalxpress.com/news/2020-01-hiv-therapy-infants.html

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