

BREATHER (PENTA 16) short-cycle therapy (SCT) (5 days on/2 days off) in young people with chronic human immunodeficiency virus infection: an open, randomised, parallel-group Phase II/III trial

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Declared competing interests of authors: Jamie Inshaw, Anna Turkova, Nigel Klein, Sarah Bernays, Julia Kenny, Eleni Nastouli, Karen Scott, Lynda Harper, Sara Paparini, Rahela Choudhury, Tim Rhodes, Abdel Babiker and Diana Gibb report grants from the PENTA Foundation during the conduct of the study. Jamie Inshaw, Anna Turkova, Nigel Klein, Julia Kenny, Eleni Nastouli, Karen Scott, Lynda Harper, Rahela Choudhury, Abdel Babiker and Diana Gibb report grants from the European Commission (FP7) during the conduct of the study.

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Plain English summary

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Plain English summary

Human immunodeficiency virus (HIV) is controlled when there is a sufficient level of effective HIV drugs in a person's bloodstream. For most drugs this means taking them every day, which is challenging for people living with HIV. Efavirenz stays in the bloodstream for longer than most HIV drugs. The BREATHER trial tested whether or not young people could safely have a weekend break from taking their HIV drugs if they took a combination containing efavirenz every weekday. Previous smaller studies in adults investigating weekend breaks in HIV treatment showed that this was possibly a safe and effective strategy in adults taking efavirenz. The BREATHER trial was designed to further test this strategy in a larger group of children, adolescents and young adults. Participants were invited to join a substudy that, using in-depth interviews, focused on the impact of the weekend breaks on their quality of life.

In total, 199 HIV-infected people aged 8–24 years from 11 countries participated. These participants were already on HIV treatment and had very low virus levels in their blood. They were randomly (like tossing a coin) divided into two groups, with half continuing daily drugs and half taking 'short-cycle therapy' (SCT), which involved taking drugs for 5 days with 2 drug-free days each week (generally at weekends).

After 1 year, those in the SCT group were as likely to have their virus under control as those taking drugs every day. Very few in either group had a substantial increase in HIV level (six in the SCT group and seven in the continuous therapy group). There was no significant difference in side effects or drug resistance between the groups.

With appropriate support, SCT may be an option for well-adherent older children, adolescents and young adults on efavirenz. Follow-up will continue until mid-2016 to see whether or not SCT remains safe and effective over the longer term.

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