

Results From the ISLEND-2 Study After 48 Weeks: Comparing ISL/LEN Once a Week With Standard Daily Treatment in People With HIV

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Background

ISL/LEN is a new drug combination being studied for the treatment of HIV. It combines the medicines islatravir (ISL) and lenacapavir (LEN) in a single tablet taken once a week.

Standard HIV medicines taken by mouth are usually taken once a day. A treatment that only needs to be taken once a week may be helpful for people who prefer not to take HIV medicine every day and wish to avoid long-acting injectable treatment.

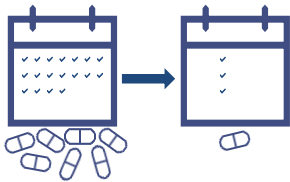
In the ongoing ISLEND-2 study, researchers are assessing how well ISL/LEN taken once a week works and how safe it is compared with standard HIV treatment taken every day.

This summary presents the main findings from ISLEND-2 after 48 weeks, which was the study's halfway point.

Why did researchers do this analysis?

Researchers want to know how well ISL/LEN taken once a week works and how safe it is when compared with standard HIV treatment taken every day.

Switch from daily to weekly treatment



Who took part in the study and how was the treatment studied?

ISLEND-2 included **626 adults with HIV** from 100 sites around the world. These people already had well-controlled HIV as shown by very low levels of HIV in their blood while taking standard HIV treatment every day.



Study participants



14% aged at least 65 years



• 42% White
• 31% Black
• 19% Asian



• 66% male at birth
• 34% female at birth

This summary looks at how well the treatments worked and how safe they were after 48 weeks. Researchers looked at the following questions:



How many participants had **undetectable HIV levels** in their blood?



How many **CD4 cells** and **lymphocytes** did participants have compared with at the start of the study?



How many participants had **side effects** (that may or may not have been related to the treatment)?



How many participants were **satisfied with ISL/LEN treatment**?

HIV levels

If an HIV treatment works, the amount of virus in a person's blood drops to levels that are too low to be measured precisely by routine tests. This is also known as undetectable.

CD4 cells and lymphocytes

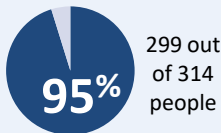
HIV attacks the body's immune system. It destroys white blood cells called lymphocytes, including CD4 cells that help the body fight infections. Higher numbers of CD4 cells and lymphocytes in the blood mean the immune system is working better.

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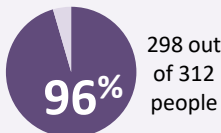
What were the results of the study?

How many participants in the study had undetectable HIV levels after 48 weeks?

ISL/LEN once a week:



Standard HIV treatment every day:



Most participants who took ISL/LEN or standard HIV treatment had undetectable levels of HIV after 48 weeks of treatment. This means the virus was suppressed. The treatments worked similarly well.

How did the treatments affect the numbers of CD4 cells and lymphocytes?



CD4 cells and lymphocytes remained stable in both treatment groups over 48 weeks. No one stopped the study because CD4 cell or lymphocyte levels became too low.

How many participants in the study experienced side effects?



The total number of participants who had side effects was similar in both groups: 79% with ISL/LEN and 77% with standard HIV treatment. Side effects thought to be related to treatment were more common in the ISL/LEN group, which may be because people in this group knew they were on a new treatment.

58 out of 314 participants (18%) had side effects thought to be related to ISL/LEN. The most common side effects were:

- Headache (in 15 participants)
- Diarrhea (in 10 participants)
- Feeling sick (nausea; in 9 participants)

1 out of 312 participants (less than 1%) had a side effect of bruising (contusion) thought to be related to standard HIV treatment

Very few participants in either group stopped the study treatment because of side effects:



2 out of 314 participants (1%) stopped taking ISL/LEN because of side effects^a



1 out of 312 participants (less than 1%) stopped taking standard HIV treatment because of a side effect^b

- 1 participant had a serious side effect (a seizure) that was thought to be related to ISL/LEN^c
- There were 3 deaths—1 in the ISL/LEN group and 2 in the standard HIV treatment group—but none were related to the treatment

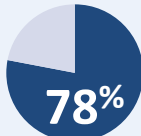
^aThese side effects were high bilirubin levels in the blood (hyperbilirubinemia; 1 participant) and new hepatitis B infection (1 participant); only the hyperbilirubinemia was thought to be related to ISL/LEN. ^bThis side effect was a type of cancer that affects the brain and spinal cord (central nervous system lymphoma; 1 participant), which was not thought to be related to standard HIV treatment. ^cThis participant had a history of seizures.

How many participants were satisfied with ISL/LEN treatment?



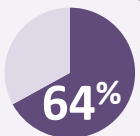
Participants were more satisfied with ISL/LEN and found it easier to manage than standard treatment.

Treatment satisfaction^a



Most participants were "much more satisfied" or "more satisfied" with ISL/LEN than with standard HIV treatment.

Treatment burden^a



Most participants felt that standard HIV treatment was harder to manage than ISL/LEN.



Tablet counts suggested that participants had remembered to take most of their weekly ISL/LEN doses (98 out of 100 doses).

^aResponses were from people taking ISL/LEN in the study; results were not available for 17 out of 314 people.



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Conclusions

After 48 weeks of the ISLEND-2 study, researchers found that:

- ISL/LEN taken once a week was as effective as standard HIV treatment taken every day at keeping HIV levels very low. This means the virus remained suppressed
- CD4 cell and lymphocyte levels stayed stable, with no important changes in either treatment group
- Most participants tolerated ISL/LEN well. Very few participants stopped treatment because of side effects
- Participants were more satisfied with ISL/LEN and found it easier to manage than standard HIV treatment

These results suggest that ISL/LEN taken once a week may be an effective treatment for HIV.

Reference: Colson AE, et al. AIDS 2026, Presentation OAX1106LB

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