TreatmentUpdate 253

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I ANTI-HIV AGENTS

A. Emerging experimental therapies

In this issue of *TreatmentUpdate*, we summarize results of recent clinical trials that sought to explore the effects of combinations of drugs. Many of these drugs are experimental and the clinical trials were of relatively short duration. It will likely be several years before one or more of them are approved as they make their way through clinical trials.

Some of these drugs are new compounds, while others are super antibodies (technically called broadly neutralizing antibodies, or bNAb). These antibodies bind to HIV, and in laboratory studies with cells or animals they are usually highly effective at stopping HIV from infecting cells. Preliminary studies in people have found that some antibodies are highly effective. Not every person with HIV has virus that is highly susceptible to these antibodies.

In addition, pharmaceutical companies are investigating long-lasting formulations of HIV treatments. For instance, the drug cabotegravir is used together with another drug called rilpivirine—both drugs injected every one or two months (depending on what the doctor and patient decide) for HIV treatment. The combination is sold as Cabenuva in North America. The developer of these drugs, ViiV Healthcare, is investigating a longer-acting formulation that can be given every four months.

Another company Gilead Sciences has developed a drug called lenacapavir (Sunlenca) that can be given every six months by subcutaneous injection (just under the skin). However, lenacapavir needs to be paired with another drug that is also

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long-lasting. A search for such a partner drug is underway. Gilead also has a new integrase inhibitor under development.

Researchers who are independent of these two companies have called for a treatment regimen that combines two long-acting formulations—cabotegravir and lenacapavir—even though both drugs have different dosing schedules. A large clinical trial will be needed to find out if the use of two drugs with different dosing schedules (every two vs. every six months) is practical for patients.

Note that we currently have limited details about experimental combinations of drugs and antibodies.

Much research is needed to find out more about the long-term effectiveness of super antibodies and for whom they will be most suitable.

B. Long-acting ART in people with adherence challenges

A major goal of HIV treatment (antiretroviral therapy, ART) today is to achieve and maintain a suppressed viral load in the blood. Some people with HIV are not able to reach this goal because they face barriers to daily pill taking, the most common mode of HIV treatment.

Researchers with the government-funded AIDS Clinical Trials Group (ACTG) conducted a study comparing the effect of injectable long-acting formulations of cabotegravir + rilpivirine (collectively called Cabenuva in North America) to that of standard oral ART. Overall, they found significantly fewer cases of virological failure in people on injectable ART.

Study details

Participants were adults who had a history of challenges to adherence on oral ART and who did not have chronic hepatitis B virus (HBV). The drugs in Cabenuva do not have anti-HBV activity. Also, participants did not have HIV that was resistant to integrase inhibitors (the class of drugs to which cabotegravir belongs) or non-nucleoside analogues (the class of drugs to which rilpivirine belongs).

Potential participants were not excluded if they were experiencing homelessness or using substances.

The design of the trial was relatively complex but involved several steps after which participants were randomly divided into the following two groups where they received different treatments for 48 weeks:

- Group A – long-acting cabotegravir + rilpivirine injected every four weeks
- Group B – standard-of-care oral ART

After one year all participants were offered injectable ART.

Researchers enrolled 434 participants with the following average profile when they entered the study:

- age – 40 years
- 70% male, 30% female; 5% were transgender persons
- main ethno-racial groups: Black – 64%; White – 27%;
- CD4+ count – 270 cells/mm^3
- viral load – 32% had a viral load less than 200 copies/mL; 25% had a viral load between 201 and 10,000 copies/mL; 28% had a viral load between 10,001 to 100,000 copies/mL; 14% had a viral load greater than 100,000 copies/mL
- time since HIV diagnosis – 13 years
- proportion of people who were currently using or had a history of injecting drugs – 14%

Results – safety

Researchers were able to analyze data from 135 people on the safety of injectable ART. They found that 57% had mostly mild-to-moderate adverse events related to the injection site, including pain, tenderness and the formation of a nodule. These were all temporary.

Overall, 93% of participants received their injections on time, 3% missed injection appointments, and 3% delayed receiving injections (figures do not total 100 due to rounding).

Focus on virological failure

The distribution of people with virological failure after 48 weeks was as follows:

- injectable ART – 7%
- oral ART – 25%

This difference was statistically significant.

The proportion of people with treatment failure (defined in this study as discontinuation of treatment due to an adverse event or virological failure) was distributed as follows:

- injectable ART – 10%
- oral ART – 26%

The proportion of people who permanently discontinued treatment was as follows:

- injectable ART – 21%
- oral ART – 25%

Taking all of these results into account, the committee overseeing the study recommended that the trial be halted and all participants were offered injectable ART.

Focus on confirmed virological failure

The cases of confirmed virological failure were as follows:

- injectable ART – 6 people
- oral ART – 28 people

Only two people in each group had new resistance mutations to integrase inhibitors.

The researchers conducting the study stated that injectable ART demonstrated overall "superiority" to standard oral ART in people who have adherence challenges and a prior history of not responding to treatment.

REFERENCE:

Rana AI, Bao Y, Zheng L, et al. Long-Acting Injectable CAB/RPV Is Superior to Oral ART in PWH With Adherence Challenges: ACTG A5359. *Conference on Retroviruses and Opportunistic Infections*, March 3-6, 2024. Abstract 212.

C. GS-1720 – a new integrase inhibitor taken once weekly

GS-1720 is a new integrase inhibitor being developed by Gilead Sciences. At this point, it is being studied in oral doses taken once weekly. The drug has been tested in people with and without HIV, but we will focus on the results in people with HIV. Participants with HIV had not previously taken integrase inhibitors and/or had not taken HIV treatment (antiretroviral therapy, ART) for at least 12 weeks.

Different doses of GS-1720 were tested—30 mg, 150 mg, 450 mg and 900 mg, given as one dose only once. There were seven people with HIV assigned per dose. Their average profile at the start of the study was as follows:

- age – 33 years
- 89% male, 11% female
- major ethno-racial groups: White – 32%; Black – 21%
- CD4+ count – 370 cells/mm^3
- viral load – 79,000 copies/mL
- 82% of participants had never previously taken ART
- no participants had resistance to integrase inhibitors

Results

Overall, there was about a 2-log decrease (100-fold) in HIV viral load. So far, no resistance was reported to have developed after a single dose of the drug. This confirms that weekly dosing should be effective when given in combination with another drug.

Researchers did not provide details but noted that four participants experienced temporary nausea, headache or vomiting, which sometimes occurs with exposure to HIV treatment.

Further studies are planned for GS-1720 to be given in combination with another drug(s) as part of once-weekly dosing.

REFERENCE:

Fichtenbaum CJ, Berhe M, Bordon J, et al. Antiviral Activity, Safety, and Pharmacokinetics of GS-1720: A Novel weekly oral integrase strand transfer inhibitor. *Conference on Retroviruses and Opportunistic Infections*, March 3-6, 2024. Abstract 116.

D. MK-8527 – a new translocation inhibitor

HIV nucleoside reverse transcriptase translocation inhibitors (NRTTI) are a new class of drugs designed to interfere with HIV-infected cells at several points in the viral life cycle. The first translocation inhibitor was islatravir, which is still in clinical trials. At high doses, islatravir was found to significantly depress lymphocyte levels. It is being tested at much lower doses and this problem has not recurred. An analogue of islatravir is MK-8527. It is taken orally once daily and does not have potential to cause many drug interactions. It is being considered for once-weekly and perhaps once-monthly dosing.

MK-8527 has been tested for preliminary safety in adults in single doses of 1, 3 and 10 mg in one study (study A). In another study (study B), lower doses were tested (1, 0.5 and 0.25 mg).

All 37 participants had not previously received HIV treatment and had a viral load that ranged between 2,000 and 720,000 copies/mL.

Results

In study A, doses of 3 and 10 mg caused a significant decrease in viral load of about 1.5 logs.

In study B, overall, there was a decrease of more than 1 log in viral load and this was maintained for 10 days after dosing.

The drug was well tolerated. Although 12 people reported headache and other symptoms, these were judged not to be related to MK-8527.

No serious adverse effects were reported, no changes to electrocardiograms were found and no one died.

Further studies are planned with this novel compound.

REFERENCES:

Gillespie G, Carstens RP, Zang X, et al. Safety and Pharmacokinetics of MK-8527, a Novel nRTTI, in Adults without HIV. *Conference on Retroviruses and Opportunistic Infections*, March 3-6, 2024. Abstract 129.

Carstens RP, Kapoor Y, Vargo R, et al. Single Dose Administration of MK-8527, a Novel nRTTI, in Adults With HIV-1. *Conference on Retroviruses and Opportunistic Infections*, March 3-6, 2024. Abstract 115.

E. Islatravir + lenacapavir once weekly

Islatravir is an experimental nucleoside reverse transcriptase translocation inhibitor (NRTTI). Lenacapavir is an approved drug that belongs to a class called capsid inhibitors.

Researchers are testing the combination of islatravir + lenacapavir, both drugs given once weekly in oral formulations. In one study, researchers gave 106 participants the following regimens:

- islatravir 2 mg + lenacapavir 300 mg – both drugs once weekly
- Biktarvy – one pill once daily containing bictegravir + TAF (tenofovir alafenamide) + FTC (emtricitabine)

After 48 weeks all participants would take islatravir + lenacapavir.

The average profile of participants upon study entry was as follows:

- age – 40 years
- 82% male at birth, 18% female at birth; 1 transgender female and 1 non-binary person
- major ethno-racial groups: White – 50%; Black – 36%
- CD4+ count – 786 cells/mm^3
- viral load – at screening for study eligibility, all but one participant had a suppressed viral load (less than 50 copies/mL) on a standard-of-care oral regimen

Results

Interim results after 24 weeks are available for most participants. In total, 94% of participants on each regimen had suppressed HIV.

One person taking islatravir + lenacapavir had a viral load of 241 copies/mL prior to initiating the regimen, and at week 24 their viral load was 64 copies/mL. By week 30, their viral load had fallen to less than 50 copies/mL and they remain in the study. This person has no detectable resistance to

the study drugs and levels of medicines in their blood are adequate for suppressing HIV.

Adverse events

Overall, more adverse events occurred in people who were taking islatravir + lenacapavir (17%) compared to Biktarvy (6%). However, all adverse events were mild or moderate in severity.

Noteworthy: Two people taking islatravir + lenacapavir had dry mouth and nausea. However, these issues were not severe.

Abnormal lab test results were generally mild and slightly more common in people taking islatravir + lenacapavir (five people) than Biktarvy (four people). One person on the two-drug regimen had elevated levels of the liver enzyme ALT in their blood, but this occurred because they had developed hepatitis B virus (HBV).

CD4+ counts and lymphocyte levels remained stable regardless of which combination participants took. This is important because several years ago a study using high daily doses of islatravir found decreased lymphocyte and CD4+ cell counts occurred. It is reassuring that this was not an issue in the current study.

The study results are promising and support continued research with the combination of islatravir + lenacapavir taken once weekly.

REFERENCE:

Colson A, Crofoot G, Ruane PJ, et al. Efficacy and Safety of Weekly Islatravir Plus Lenacapavir in PWH at 24 weeks: A Phase II Study. *Conference on Retroviruses and Opportunistic Infections*, March 3-6, 2024. Abstract 208.

F. Lenacapavir + super antibodies

Super antibodies (so-called broadly neutralizing antibodies, or bNAb) have been developed that are generally highly active against HIV in experiments with cells and viruses in the lab as well as in animals. These antibodies bind to HIV and prevent it from attaching to the CD4 receptor on cells; as a result, HIV is not able to infect a cell.

Gilead Sciences is developing the following two bNAbs:

- teropavimab (Tab)
- zinlirvimab (Zab)

Both antibodies persist a long time after administration (intravenously), which allows for dosing every six months.

Gilead is testing a combination of these antibodies with the antiviral drug lenacapavir (a capsid inhibitor). In lab experiments with cells, the combination of all three agents has been found to be potent. Preliminary testing in people also suggests that these drugs combined have a high level of effectiveness. In one study, 18 out of 20 people were able to maintain virological suppression for six months after dosing.

A drawback of antibody-based therapy is that participants have to be tested before using it to find out if their HIV is susceptible to the antibodies. Such testing is not yet routine.

In one study, researchers enrolled participants who were susceptible to at least one of the antibodies. Participants who were already suppressed on oral regimens (of other drugs) were randomly assigned to one of the following long-acting regimens:

- lenacapavir + Tab 30 mg/kg of body weight + Zab 10 mg/kg – 5 people
- lenacapavir + Tab 30 mg/kg + Zab 30 mg/kg – 6 people

They stopped their oral regimens and immediately received the study regimens.

Drugs were injected once and participants were monitored for 26 weeks. After that they would restart standard oral ART (taken daily).

Lenacapavir was given orally at a dose of 600 mg on days 1 and 2 of the study. It was also injected subcutaneously at a dose of 927 mg on day 1.

Antibodies were given intravenously on day 1.

One person taking Zab 10 mg left the study because they developed chronic hepatitis B virus infection (HBV). All other participants completed the study.

The average profile of participants upon study entry was as follows:

- age – 49 years
- 3 females and 8 males
- weight – 86 kg
- CD4+ count – 916 cells/mm^3
- duration of prior ART – 4 years
- time since HIV diagnosis – 16 years

Results – safety

All adverse events were related to the subcutaneous injection of lenacapavir, including redness, pain, swelling and itchy skin. These were mild and temporary. No adverse events were linked to the infusion of antibodies. There were no abnormal lab test results.

Virological results

All six people taking the higher dose of Zab (30 mg/kg) maintained virological suppression throughout the study. In contrast, only two out of five people who took the lower dose of Zab (10 mg/kg) were able to maintain virological suppression.

All participants had high concentrations of antibodies in their blood.

Focus on virological rebound in two people

One participant had HIV that was partially susceptible to Tab. He maintained suppression until about week 25 of the study and then his viral load rose to 72 copies/mL. He then resumed his previous oral ART regimen and HIV became suppressed.

Another person had HIV that was susceptible to Tab but became less susceptible to Zab. She had low levels of detectable HIV from the start of the study. During the study, her viral load rose to 112 copies/mL and then subsequently fell to 55 copies/mL at week 26. She resumed oral ART but her viral load became detectable again a year later, though it was less than 100 copies/mL.

Resistance to treatments was not detected in either of these people.

Bear in mind

The combination of lenacapavir and super antibodies was generally safe, and the higher dose of Zab was more effective. Further clinical trials are planned in people who have HIV that is highly susceptible to both antibodies.

REFERENCE:

Eron JJ, Cook PP, Mehrotra M, et al. Lenacapavir Plus bNAbs for People With HIV and Sensitivity to Either Teropavimab or Zinlirvimab. *Conference on Retroviruses and Opportunistic Infections*, March 3-6, 2024. Abstract 120.

G. N6LS – a new super antibody

A super antibody called N6LS (code named VH3810109) is being developed by ViiV Healthcare. It has recently been tested in a phase II study in people who have not previously used HIV treatment. The antibody binds to HIV and blocks it from attaching to CD4 receptors on T-cells. A previous study suggests that it has potent anti-HIV activity in people and is generally well tolerated.

Usually, prior to entering an antibody-based study, participants are screened for HIV that is susceptible to the antibody. However, in the present study, perhaps because of difficulty obtaining the screening assay, participants' blood samples were screened after the study began.

In the present study, the antibody was given via intravenous infusion or subcutaneous injection.

Researchers tested a single application of the antibody to assess its anti-HIV effect. Doses of the antibody included the following:

- 700 mg given intravenously (10 mg/kg)
- 70 mg given intravenously (1 mg/kg)
- 700 mg given via subcutaneous injection (10 mg/kg)

The average profile of the 62 people who entered the study was as follows:

- age – 30 years
- 94% male, 6% female
- major ethno-racial groups: White – 61%; Black – 18%
- CD4+ count – 383 cells/mm^3

- viral load – 25,000 copies/mL
- body mass index (BMI) – 25 kg/m^2

Results

In general, the higher the dose of antibody, the greater the suppression of HIV. The dose of 10 mg/kg given intravenously resulted in about a 1.5-log decrease in viral load. When the antibody was given via subcutaneous injection, viral load did not fall significantly.

Researchers are planning another study called "Embrace" with the antibody in combination with the drug cabotegravir. In Embrace, researchers plan to also use an enzyme called hyaluronidase. This enzyme allows the body to store greater amounts of fluid when injected subcutaneously. In Embrace, researchers hope to screen people for having HIV that is susceptible to the antibody prior to starting study drugs.

REFERENCE:

Leone P, Ferro A, Lupo S, et al. VH3810109 (N6LS) in Adults With HIV-1 Who Are ART-Naive: Phase IIa BANNER Efficacy Data. *Conference on Retroviruses and Opportunistic Infections*, March 3-6, 2024. Abstract 117.

H. Super antibodies – bear in mind

As mentioned earlier in this issue of *TreatmentUpdate*, there are several super antibodies (also known as broadly neutralizing antibodies, or bNAb) in development. These are antibodies that have been designed to be highly specific at attaching to HIV and preventing it from infecting cells. They are all experimental and have not been approved for HIV treatment or prevention. In clinical trials, some of these super antibodies can help keep HIV suppressed, at least for a time.

The best role for super antibodies is not yet known and many clinical trials lie ahead. One advantage is that they only need to be administered every six months, usually by intravenous infusion.

Below are some points to bear in mind about super antibodies:

Screening
Prior to using them, people will need to be screened for HIV that is susceptible to the antibodies. If the antibodies are approved, the cost of screening will need to be relatively cheap or be borne by the pharmaceutical company.

Cost
Highly specific and effective antibodies have been developed for inflammatory conditions (such as arthritis, Crohn's and colitis, psoriasis) and cancer. In these cases, pharmaceutical companies charge high prices for these therapies. If bNAbs are ever approved for HIV prevention and treatment, it is not clear how much they will cost.

Administration
Antibodies need to be given intravenously or via subcutaneous injection (just under the skin). Some people prefer not to experience injections, so it is not clear how widely used antibody-based therapy will become.

One, two or three?
How many antibodies are optimal? HIV can mutate quickly inside infected cells and develop resistance to one antibody. Therefore, super antibodies may be prioritized for people whose viral load is already suppressed or otherwise low. It is likely more difficult for HIV to easily develop resistance to two or more antibodies when used simultaneously. What is not known is the optimal number of super antibodies that should be administered to people. Should infusions include at least two or three antibodies, all given on the same day?

A virus that can hide
HIV-infected cells can lie deep within parts of the brain and lymphoid organs such as the spleen and testicles. It may be difficult for high concentrations of these antibodies to accumulate in the brain, spleen and certain other parts of the body. Thus, when super antibodies are used as part of treatment, they will likely need to be accompanied by anti-HIV drugs that can penetrate the brain, spleen and other reservoirs for the virus.

Super antibodies are also being developed to be used as part of efforts to try to cure HIV. In clinical trials, super antibodies will be part of several different approaches to curing this viral infection. Such trials are in their infancy, and the best combination of experimental drugs to use together with super antibodies in cure research is not clear.

Super antibodies are an exciting development, but studies are needed to explore the issues mentioned above and more.

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Kumar MR, Fray EJ, Bender AM, et al. Biphasic decay of intact SHIV genomes following initiation of antiretroviral therapy complicates analysis of interventions targeting the reservoir. *Proceedings of the National Academy of Sciences USA*. 2023 Oct 24;120(43):e2313209120.

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II COMPLICATIONS

A. Depression linked to increased stroke risk in some people with HIV

Due to social and biological factors, depression is relatively common in people with HIV. Some studies have found that there is a greater risk of stroke in people with HIV compared to people without HIV.

In the present study, clinics with nearly 14,000 people with HIV pooled their databases and monitored reports of stroke that occurred over eight years. Neurologists reviewed medical records to be certain that strokes occurred. Participants were regularly screened for depression using standardized surveys.

At the start of the study, the average profile of participants was as follows:

- age – 45 years
- 81% male, 19% female
- a majority of participants (58%) were people of colour and 42% were White
- comorbidities – 13% had elevated cholesterol that was being treated and 26% had high blood pressure that was being treated
- substance use – 64% used alcohol; 38% used tobacco; 8% used methamphetamine; 7% used cocaine
- 23% had symptoms of depression

Results

Over the study, 173 participants had a stroke.

Statistical analysis found that, overall, people who had depression were 16% more likely to have a stroke. This connection between depression and stroke risk was limited to people younger than 50 years old. There was a trend among young people who had greater severity in depression to have a greater risk of stroke. There was no difference in stroke risk by sex.

Bear in mind

The link between depression and stroke risk is likely complex. It may be that younger people are more likely to have inflammation that increases their risk of stroke. The researchers argue that there are factors that need further analysis, such as those related to sociodemographics, HIV and substance use. It is also possible that when people are depressed they may not have the energy to take medicines regularly and they may have problems remembering when to take them. Much work lies ahead to clarify these issues and provide guidance for clinicians caring for younger people with depression and HIV.

A recent study from Paris, France, conducted between 2017 and 2021 found that people with HIV had an elevated risk of stroke. People under the age

of 55 were more likely to have a detectable viral load, likely contributing to elevated inflammation and stroke risk.

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Ma J, Nance RM, Tirschwell D, et al. Associations Between Depressive Symptom Severity and Incident Stroke among people with HIV. *Conference on Retroviruses and Opportunistic Infections,* March 3-6, 2024. Abstract 110.

Stammler R, Guillaume J, Mazighi M, et al. First-ever acute ischemic strokes in HIV-infected persons: A case-control study from stroke units. *Annals of Clinical and Translational Neurology*. 2024; *in press*.

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