New HIV drugs show promise

MK-1439, a next generation non-nucleoside reverse transcriptase inhibitor has performed well in an early clinical trial.

The drug had a powerful anti-HIV effect and was well-tolerated.

The double-blind placebo controlled study involved 18 people with HIV who had not taken antiretroviral therapy before (treatment naive).

They were randomised to receive either one of two doses of MK-1439 (25mg or 200mg) once daily as monotherapy for seven days or a placebo.

Both doses of the drug showed a powerful anti-HIV effect. Viral load fell in the people taking MK-1439 and remained unchanged among people in the placebo arm.

Moreover, both doses of the drug achieved concentrations capable of inhibiting HIV replication.
Side-effects were reported by approximately three-quarters of study participants. But these tended to be mild and went away at the end of the study. There were no skin rashes, laboratory abnormalities or central nervous system side-effects.

A phase IIb study is now planned.

Separate research showed that the investigational joint CCR5/CCR2 inhibitor cenicriviroc had an anti-inflammatory effect as well as inhibiting HIV replication.

Investigators presented interim 24-week data from a phase IIb 48-week study. The study is comparing cenicriviroc with efavirenz.

Study participants were randomised to take one of two doses of cenicriviroc or efavirenz in combination with Truvada.

At 24 weeks, approximately three-quarters of people in each arm had an undetectable viral load.

There was a trend for larger CD4 cell increases with cenicriviroc.

Cenicriviroc appeared safe and well-tolerated. Only 2% of participants stopped therapy with the drug due to adverse events, compared to 18% of individuals in the efavirenz arm.

Investigators also found that cenicriviroc had a favourable effect on biomarkers of inflammation and was associated with a fall in LDL cholesterol.

Related links

Read the news story about MK-1439 in full on aidsmap.com (includes link to abstract)
Read the news story about cenicriviroc in full on aidsmap.com (includes link to abstract)
View a webcast of the presentation session
Results of two French studies suggest that adding the protease inhibitors boceprevir or telaprevir to standard hepatitis C therapy improved treatment outcomes in people with HIV and hepatitis C co-infection who had characteristics associated with a poor hepatitis C treatment response.

The safety profile of the two drugs was also acceptable.

Large numbers of people living with HIV are co-infected with hepatitis C, and liver disease is an important cause of death in people with this co-infection.

Some people with hepatitis C are delaying starting treatment until newer drugs become available, in particular interferon-free regimens, because of the unpleasant side-effects caused by interferon.

However, people with HIV and hepatitis C co-infection who have serious liver disease are in urgent need of new hepatitis C treatment options, such as boceprevir or telaprevir.

French investigators therefore designed two separate studies examining the safety and efficacy of adding boceprevir or telaprevir to interferon-based treatment.

The study populations involved people with co-infection who had hepatitis C genotype 1 infection and who had not responded to a previous course of interferon-based therapy.

Between 70 and 75% of the study participants had the difficult-to-treat genotype 1a infection, and up to a quarter had liver cirrhosis.

Interim results from the boceprevir study showed that 63% of patients had an undetectable hepatitis C viral load after 16 weeks of therapy. Surprisingly, 73% of patients with cirrhosis had a good treatment response at this point.

Almost all the participants in this study reported side-effects. These were categorised as serious in 30% and a small number of individuals stopped therapy early because of adverse events.

Laboratory abnormalities were also common, with 42% developing anaemia and 70% neutropenia.

Interim 16-week data were also presented for the telaprevir study. Some 88% of patients had a good treatment response at this point. However, skin reactions were common and were observed in 70% of patients. Approximately a third of patients developed anaemia and 84% developed neutropenia.

A number of promising new anti-hepatitis drugs are in the pipeline and they offer the prospect of high treatment-response rates without the need for interferon.

However, the results of these studies will offer hope for people with HIV and hepatitis C co-infection whose liver disease means that early treatment is a priority.
HIV treatment for children in resource-limited settings

HIV treatment can achieve good results in children living with HIV without routine monitoring of CD4 cell counts and laboratory markers of side-effects, results of a study conducted in Uganda and Zimbabwe show.

Researchers say that money spent on expensive laboratory tests should be directed towards expanding access to HIV treatment. According to UNAIDS estimates, only 28% of children in need of HIV treatment were receiving it in 2011.

The study involved 1200 HIV-positive children taking first-line antiretroviral therapy. They were aged between four months and 17 years and had moderately advanced immune suppression.

They were randomised into two arms. Those in the first group had laboratory tests every twelve weeks, including a full blood count and CD4 cell counts. Children experiencing a 30% fall in their CD4 cell count or who experienced HIV disease progression were switched to second-line treatment.

The children in the second group were also monitored every twelve weeks. But they only had laboratory tests if these were specifically requested.

Study outcomes were HIV disease progression and the development of serious side-effects.

Survival rates were equally high in the two study arms, and equal proportions of children remained on their first-line treatment combination. Nor was there any difference in the frequency of serious side-effects.

The study also showed that laboratory monitoring was not cost-effective. The researchers urge that laboratory resources should be focused on carrying out tests that are clinically indicated, rather than routinely monitoring all patients.
They concluded that HIV therapy for children in resource-limited settings was highly effective and safe without routine clinical monitoring.

Related links
- Read this news story in full on aidsmap.com
- View the study abstract on the conference website
- View a webcast of the presentation session

Safety of HIV treatment during pregnancy

Jeanne Sibiude of Louis Mourier Hospital, France, presenting at CROI 2013.

A large French study has provided information about the safety of HIV treatment during the first trimester of pregnancy and the association between specific anti-HIV drugs and the risk of birth abnormalities.

It showed that treatment with efavirenz (Sustiva, also in Atripla) was associated with an increased risk of neurological abnormalities.

Infants exposed to AZT (zidovudine, Retrovir) had an increased risk of heart defects.

Therapy with either ddl (didanosine, Videx) or 3TC (lamivudine, Epivir) was associated with increased rates of head and neck defects in babies.

The study involved over 13,000 infants, born to mothers with HIV, and who were exposed to anti-HIV drugs while in the womb.

The overall prevalence of birth abnormalities was between 4 and 8%.

However, the total number of any abnormality associated with any specific drug, other than AZT, was small. Moreover, the increase in relative risk was modest.

The study largely confirmed what is already known.

Despite its findings, the benefits of HIV treatment during pregnancy still outweigh the risks, reducing the risk of mother-to-child transmission to very low levels and protecting the health of
the mother.

But the findings have rekindled debates about the association between efavirenz and the risk of birth abnormalities.

The drug had been associated with birth abnormalities in animal studies and was therefore not recommended for use during pregnancy. However, this recommendation was revised in 2011, after a large meta-analysis showed no excess risk of such defects.

On the basis of the present results, Jeanne Sibiude, for the French Perinatal Cohort, concluded that recommendations to avoid efavirenz during the first trimester should be maintained in countries where other drug options exist, but other experts at the meeting emphasised that the risks needed to be balanced against the benefits to mother and child of antiretroviral therapy that contains efavirenz.

Related links

- Read this news story in full on aidsmap.com
- View the study abstract on the conference website
- View a webcast of the presentation session

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There are so many organisations around the world doing so much amazing work to treat, support and care for people affected by HIV. It is vitally important that these organisations can talk to and learn from one another so that valuable resources aren’t wasted reinventing the wheel.

Our online e-atlas maps out over 2500 HIV organisations, clinics and services worldwide and profiles the work they do. This is the most comprehensive listing of HIV services available anywhere and the number of people contributing to this resource grows every day. NAM works to provide an essential platform through which people can share their research and experience; upload resources; and network and collaborate with others.

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