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Four-in-one AIDS drug gets the OK in clinical trial

PARIS: An experimental once-daily pill that combines four drugs to fight HIV is as safe and effective as commonly-prescribed treatments against the AIDS virus, researchers reported in *The Lancet*.

Doctors tested the new drug, called Quad, for the third and final phase in which new pharmaceutical products are vetted for safety and effectiveness.

Publication in the British journal follows a recommendation in May by a US Food and Drug Administration (FDA) advisory panel to approve Quad for previously untreated adults infected with HIV-1. A final decision is expected by August.

The first trial entailed testing Quad against a three-in-one pill, Atripla, which since 2006 has been a standard treatment for the human immunodeficiency virus (HIV).

Researchers enrolled 700 patients in centres in North

America and assigned them randomly to either Quad or Atripla.

After 48 weeks of treatment, 88 per cent of Quad patients had suppressed viral loads to below detectable levels, against 84 per cent in the Atripla group.

Side effects were infrequent but similar in both groups. Among Quad patients, mild nausea was the more common adverse event, whereas with Atripla, symptoms were likelier to be dizziness, abnormal dreams or insomnia and skin rashes.

In the second trial, 708 patients were enrolled in Australia, Europe, North America and Europe.

Patients were either given Quad or a widely recommended therapy comprising the molecules atazanavir (ATV), boosted by ritonavir (RTV), together with emtricitabine (FTC) and tenofovir disoproxil fumarate, or TDF.

After 48 weeks, 90 percent of the Quad group had viral levels below

detectable levels compared to 87 percent in the other drug group.

Only 3.7 percent of patients in the Quad group stopped treatment because of side effects, compared with 5.1 percent in the other group. On the other hand, the number who reported kidney complications in the Quad group was relatively higher.

Quad comprises FTC and TDF, along with a drug called elvitegravir (ETV), which is designed to inhibit HIV replication. The fourth ingredient is a "pharmacoenhancer" called cobicistat to boost the effectiveness of ETV.

The movement towards a single once-daily pill to suppress HIV has a huge benefit for patients, say, AIDS researchers.

When the first antiretroviral drugs emerged in the 1990s, patients had to take a dozen tablets a day or more, a "pill burden" that meant many forgot to follow the entire treatment. — AFP