Studied as a way to reduce excess deep belly fat, the synthetic human growth hormone releasing factor called tesamorelin may be approved by the FDA in the first half of 2010. Results from a 52-week study of 816 people showed 18% less deep belly fat in those on tesamorelin than those on placebo.

Although it may help some people trim down some of their deep belly or visceral fat, it should not be viewed as a weight control product. In HIV people this fat has been shown to increase a person’s risk for heart disease. Tesamorelin does not affect subcutaneous fat, or the fat that’s found above the stomach muscles but below the skin.

Body shape changes

Many people with HIV, about 1 in 4, face a condition called lipodystrophy. The syndrome is due to several causes that can overlap and are not well distinguished by research. How to treat the condition can also become a complex set of decisions made you and your doctor.

The symptoms of lipodystrophy can vary from person to person. Some have fat loss, usually in the face, arms or legs (lipoatrophy). Others have fat gain, particularly on the neck or around the breasts or abdomen (lipohypertrophy). These visible symptoms can be accompanied by higher levels of blood fats (dyslipidemia) and by changes in insulin or blood sugar (hyperglycemia).

One common symptom, excess deep belly fat, can be troublesome. Not only do many feel uncomfortable and conspicuous with a larger belly, it can also prove painful to some or restrict others from being as active as they once were. This visceral fat lies beneath the stomach muscles near the internal organs, increasing the risk for heart disease. The condition can result from genetic factors, diet, HIV-related drugs and from HIV itself.

Study volunteers

In a Phase 3 study, 550 people were given 2mg tesamorelin while 266 were given placebo, by injection once a day. Adherence to the regimen was 99% or higher for both groups. All had CD4s above 300, and 3 in 4 had undetectable viral loads. Average time on HIV therapy was 4.5 years, average time since diagnosis of visceral fat was 4 years, and average age was 48. Average waist size was 41 inches.

The average time living with HIV since diagnosis was about 13 years. More than 4 in 5 were men. Study volunteers used several different HIV regimens: NNRTIs + NRTIs (33%), protease inhibitors + NRTIs (45%), NNRTIs + NRTIs + protease inhibitors (10%), NRTIs only (5%), or other regimens (7%).

Study design

The goal of the study was to assess how much fat loss would occur from using tesamorelin compared to placebo (first 26 weeks). For the second 26 weeks, everyone on placebo was given tesamorelin while those who had already taken the drug were then randomized to continue on it or start taking placebo. Body scans were taken before starting therapy, during the study, and at the end of 52 weeks. Other tests were also taken, such as those for cholesterol, triglycerides, glucose, insulin and belly image.
Tesamorelin and excess deep belly fat

Side effects

Side effects were similar between the two groups, though more volunteers quit the tesamorelin group than those on placebo. Injection site redness and itchiness were common. Joint pain and general aches and pains were also noted by volunteers.

One concern from using tesamorelin is the build-up of its antibodies in some people. Nearly all those with skin reactions tested positive for these antibodies. Their significance is unknown at this time, but the concern is that they could reduce the effects of the tesamorelin over time. During this study, these antibodies didn't appear to be “neutralizing” in this way, but more follow-up needs to be done.

Results

At 26 weeks, tesamorelin reduced deep belly fat by 13% compared to placebo. At 52 weeks, for those who continued on the drug, tesamorelin reduced it by nearly 18%. Those who took tesamorelin for 26 weeks and then placebo for 26 weeks showed a reverse in symptoms, with gaining the deep belly fat back rather quickly.

Tesamorelin did not significantly change either cholesterol or blood sugar levels. However, it did significantly reduce triglycerides, which help lower the risk for heart disease. It also increased insulin-like growth factor, which aids the body to better use energy that may result in less stored fat.

People who were on regimens of NRTIs + protease inhibitors or NRTIs-only had slightly higher rates of visceral fat loss. Another benefit from using tesamorelin appears to be a small increase in lean body mass, but nowhere near the levels seen with the human growth hormone called Serostim.

As for the self-assessment, the data are still positive though not as convincing. Three scores were assessed at the start and end of the study: the level of distress a person felt by his/her belly image, the doctor’s assessment of the change in belly fat, and the person’s assessment of that same change.

Volunteers generally felt better about their belly image after using tesamorelin compared to placebo, though it was only slightly better. Similarly, doctors believed there was some improvement in fat. However, volunteers using tesamorelin did not believe a noticeable change occurred in the size of their bellies.

Project Inform’s perspective

The reasons why a person wants to use tesamorelin may be more of a deciding factor in treating deep belly fat. While it may get rid of some visceral fat to ease the discomfort, pain or immobility that some people face, the modest reduction may not be enough to feel better about one’s belly size. However, getting rid of some of this fat may be enough to ease the discomfort that some people face with excess deep belly fat.

These studies treated people with excess deep belly fat, so should it be approved by the FDA it may not be prescribed for people with low or even moderate levels of visceral fat. It’s also unknown how much more benefit or even what side effects can occur from using it for more than a year, such as the appearance of tesamorelin antibodies. Also, the cost of tesamorelin is unknown at this time and may be challenging for some should it get FDA approval.

More study is needed to see if various doses of tesamorelin could achieve the same (or better) results, including cycling on and off the drug. This could reduce the number of injections over time. For now, to keep the visceral fat from coming back, people are faced with injecting themselves every day, which some are not willing or equipped to do.