

Risk List for Informed Consent

General Disclaimer

The drugs used in this study may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with these drugs. These lists include the more serious or common side effects with a known, or possible relationship. If you have, questions concerning the additional study drug side effects please ask the medical staff at your site.

Use of Combination Antiretroviral Drugs

Immune Reconstitution Syndrome: In some people with advanced HIV infection, signs and symptoms of inflammation from other infections may occur soon after anti-HIV treatment is started.

The use of potent antiretroviral drug combinations may be associated with an abnormal placement of body fat and wasting. Some of the body changes include:

- Increase in fat around the waist and stomach area
- Increase in fat on the back of the neck
- Thinning of the face, legs, and arms
- Breast enlargement

Nucleoside Analogue

Lactic acidosis (elevated lactic acid levels in the blood) and severe hepatomegaly (enlarged liver) with steatosis (fatty liver) that may result in liver failure, other complications or death have been reported with the use of antiretroviral nucleoside analogues alone or in combination. The liver complications and death have been seen more often in women on these drug regimens. Some nonspecific symptoms that might indicate lactic acidosis include: unexplained weight loss, stomach discomfort, nausea, vomiting, fatigue, cramps, muscle pain, weakness, dizziness and shortness of breath.

Didanosine (ddI, VIDEX®)

Bristol-Myers Squibb

The following side effects have been associated with the use of didanosine:

- Pancreatitis (swelling of the pancreas), which may cause death. If you develop pancreatitis, you may have one or more of the following: stomach pain, nausea, and vomiting.
- Deaths from lactic acidosis have been reported in pregnant women receiving the combination of didanosine and stavudine.
- Serious liver problems have happened in some people (including pregnant women) who take didanosine. These problems, which include liver failure and high blood pressure in the large vein of the liver, may lead to death.

- If you are developing liver problems, you may have one or more of the following:
- Yellowing of the skin or whites of your eyes
- Dark urine
- Pain on the right side of your stomach
- Easy bruising or bleeding
- Loss of appetite
- Upset stomach or vomiting
- Vomiting blood or dark colored stools

Additional side effects associated with the use of didanosine include:

- Numbness, tingling, and pain in the hands or feet
- Abnormal vision changes
- Upset stomach, vomiting and loose or watery stools
- Headache
- Abnormal pancreatic function blood tests or abnormal liver function blood test
- Increase in uric acid in the bloodstream

When didanosine is used with other medicines with similar side effects, these side effects may be seen more often and may be more severe than when didanosine is used alone. People who take didanosine together with stavudine, with or without hydroxyurea, may be at greater risk for pancreatitis or liver problems or both. These conditions may result in death.