Seronegatives And Metabolic Abnormalities Protocol 2 (SAMA 002)

ACTRN12605000661673

Status	RECRUITING
Phase	Phase 4
Sponsor	The University of New South Wales
Enrollment	50 participants

Plain Language Summary

This study is looking at how common HIV medicines — specifically Combivir (a combination of two antiretroviral drugs) and Kaletra (a protease inhibitor) — affect cholesterol, blood fats, and blood sugar levels in healthy people who do not have HIV. Understanding these metabolic effects in HIV-negative volunteers helps researchers separate the drug effects from the effects of HIV infection itself.

You may be eligible if:
- You are 18 years or older
- You have tested negative for HIV (both antibody and DNA tests)
- You are able to give written consent to take part

You may NOT be eligible if:
- You have any ongoing physical or mental health condition that would affect your ability to participate (including suspected heart disease)
- You have a history of type 1 or type 2 diabetes, or have previously taken diabetes medication
- You have used testosterone, oestrogen, growth hormone, oral steroids, or anabolic steroids in the past 6 months
- You have a history of alcohol or drug abuse
- You have previously used any antiretroviral medicines (including HIV post-exposure treatment)
- You have used retinoid-containing compounds in the past 6 months
- You are pregnant
- You have hepatitis B or hepatitis C infection
- You have abnormal blood test results from screening

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (1)

• Be able to provide written consent to perform in the trial. - HIV antibody negative and HIV DNA negative at time of entry to the study.

Exclusion (1)

• Any history of, or ongoing, mental or physical condition (including suspected or known diagnosis of ischaemic heart disease), which, in the opinion of the investigator, would impede the subjects ability to participate in the trial.- History of type I or type II diabetes mellitus or previous treatment with antidiabetic medication. - Prior use of testosterone, oestrogen, growth hormone or other oral glucocorticoid or anabolic steroid products within the previous six months. - Alcohol or substance abuse which in the opinion of the investigator would affect the subjects ability to participate in the trial. - Prior use of anti-retroviral agents (including protease inhibitors, nucleoside or non-nucleoside reverse transcriptase inhibitors, investigational antiretroviral agents or fusion inhibitors either in a previous study, as treatment or as part of post-exposure prophylaxis).- Prior use of any retinoid-containing compound within the previous six months. - Abnormal coagulation. - Previous allergic reaction or known allergy to local anaesthetic. - Previous use of psychotropic medications. - Concomitant use of medications, including those metabolised by CYP3A4 enzyme system (appendix C), which, in the opinion of the investigator, would affect the subjects ability to participate in all activities involved in the trial. - Any grade-three laboratory abnormality recorded from screening bloods. - Any grade-two

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laboratory abnormality recorded from screening bloods, which, in the opinion of the investigator, would impede the subjects ability to safely complete all study requirements. - Gastrointestinal disorders, which may affect drug absorption. - Any finding on screening clinical examination, which, in the opinion of the investigator, would impede the subjects ability to participate in the rest of the trial.- Pregnancy - Evidence of acute or chronic active hepatitis B virus infection by serology performed at baseline. - Evidence of hepatitis C infection by serology performed at baseline.

Locations (1 total)

Australia

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