HIV Infection And Metabolic Abnormalities Protocol 1 (HAMA 001)

ACTRN12605000662662

Status	RECRUITING
Phase	Phase 4
Sponsor	The University of New South Wales
Enrollment	80 participants

Plain Language Summary

This study is looking at how HIV treatment affects fat cells in the body. Researchers want to understand why some people on HIV treatment develop changes to their body shape (like gaining or losing fat in unusual places). This is done by studying fat tissue, blood tests, and body composition measurements over 48 weeks in HIV-positive people who are about to start treatment for the first time.

You may be eligible if:
- You are 18 years or older
- You have tested HIV-positive
- You are about to start antiretroviral treatment for the very first time (for Part A of the study), OR you have already been on HIV treatment for at least 48 weeks (for Part B)

You may NOT be eligible if:
- You have any significant physical or mental health condition that would affect your ability to take part
- You have used growth hormone, steroids, or high-dose testosterone/oestrogen in the past 6 months to 1 year
- You have a history of alcohol or drug abuse
- You have used retinoid-containing compounds in the past 6 months
- You have abnormal blood clotting
- You have a known allergy to local anaesthetic
- You are pregnant

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 positive at time of entry to the study.Specific to HAMA part A only:- Be naive to antiretroviral medication.Specific to HAMA part B only:- Have had a minimum total exposure to antiretroviral medications (to include drugs from more than one drug class) of 48 weeks at time of recruitment.- Have had a minimum of 48 weeks interval since completion of HAMA part A.

Exclusion (1)

• General:- 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.- Prior use of growth hormone or glucocorticoid or anabolic steroid products within the previous six months.- Prior use of supraphysiological doses of testosterone or oestrogen replacement therapy within the previous year.- Alcohol or substance abuse which in the opinion of the investigator would affect the patients ability to participate in the trial.- Prior use of any retinoid-containing compound within the previous six months.- Abnormal coagulation.- Previous allergic reaction or known allergy to local anaesthetic.- Previous or concomitant use of medications, 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, which, in the opinion of the investigator, would impede the subjects ability to safely complete all study requirements.- 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.Specific to HAMA part A only:- Prior use of anti-retroviral agents (including protease inhibitors, nucleoside or

non-nucleoside reverse transcriptase inhibitors, investigational antiretroviral agents or fusion inhibitors). Entry of individuals who have had previous antiretroviral therapy as part of Post Exposure Prophylaxis will be at the discretion of the study investigators.

Locations (1 total)

Australia