PROJECT PHIDISA

Make better, prolongs lives

INTRODUCTION

Project Phidisa is a clinical research South African Military Health Service (SAMHS) project that aims to establish the impact of HIV infection on South African National Defence Force (SANDF) members and their dependents, and to develop appropriate strategies for the effective management and prevention of HIV infection. This project is a collaborative undertaking between the governments of the Republic of South Africa and the United States of America and executed by the South African Military Health Service (SAMHS) of the SANDF, the United States Department of Defence and the National Institutes of Health (NIH) of the United States.

BACKGROUND

The Phidisa programme was established in 2003 and is likely to run until mid-2010. It is an extension of the SA DOD Masibambisane Programme, which is a SANDF initiative to address all aspects of HIV and AIDS in the DOD. The Phidisa Programme involves clinical and operational research in HIV/AIDS in the military population and their dependants.

Scientists engaged in the clinical research trials are from South Africa, the United States and Australia and are associated with military, civilian and academic institutions. The Phidisa programme was designed to help strengthen clinical research infrastructure and research and academic capacity within the SANDF and its associated network of clinics, sick bays and hospitals.

It is expected that Phidisa will contribute to important biomedical and public health research capacity and capability that can be used in the future to address health issues of critical importance for military force preparedness and combat readiness. Further, as a result of this research programme, it is hoped that important information will be generated to assist SANDF in its future decisions about how best to manage the HIV/AIDS infection rate in military settings.

RATIONALE FOR CONDUCTING THE STUDIES

In a resource-limited environment, complex decisions regarding treatment priorities must be made in order to ensure that those in most urgent need of treatment are identified most rapidly and have access to the necessary management strategies. Thus, the first part of the study, called Phidisa I (PI), is an epidemiological study; the intent of which is to support the diagnosis of HIV infection, to assess specified significant co-infections and to evaluate HIV infection risk in HIV sero-negative volunteers.

All treatment (management) guidelines acknowledge that the principal determinants of risk of HIV disease progression and death are an absolute CD4+ cell count falling below 200cells/uL or a prior AIDS defining illness. However, on a comparative basis relatively little has been evaluated about the sustainability of these regimens in terms of the following significant public health issues:

1. Which regimen is most effective?
2. Which regimen is best tolerated?
3. Which regimen is most feasible in a given healthcare setting?
4. Which regimen is associated with better cost-benefit outcomes?

Therefore, the second part of this study, known as Phidisa II (PII), will evaluate a range of public health outcomes arising from the treatment of Phidisa volunteers with CD4+ cell counts < 200 cells/μL and/or advanced HIV disease in a large randomised study with HIV disease progression or death as the primary endpoint.

**PHIDISA RESEARCH STUDIES**

The study is entirely voluntary and participants may withdraw at any time during the study.

Phidisa I is a screening protocol which in essence is an epidemiological study of HIV and AIDS, sexually transmitted diseases and the associated risk factors for developing HIV infection. The analyses of these risk factors include a comprehensive assessment of the life style and risky behaviour. Counseling on HIV prevention and management, health life style changes and other support measures are comprehensively provided. There is no ARV therapy given in Phidisa I. An added importance of this screening portal of entry, i.e., Phidisa I, is that participants are comprehensively examined for pre-existing conditions that may or may not be associated with HIV. These persons are treated for these conditions to ensure that they are in best possible health prior to them receiving ARV therapy, if applicable.

More than 5033 participants were enrolled in this part of the study as of 31 January 2007. When an HIV-positive participant meets certain well-defined criteria, this person is then referred to the HIV management and treatment arm of the study, which is Phidisa II. However, those participants who are positive but do not meet the criteria for admission to the treatment and management arm, are kept under close medical monitoring in Phidisa I to ensure the best possible care.

Phidisa II is a well controlled study, designed to compare the safety and efficacy of different combinations of anti-retroviral therapy in the management of HIV infected persons. In addition, this study (Phidisa II) also critically analyses HIV risk behaviour, health care utilisation, quality of life as well as nutritional status.

Participants in Phidisa II are followed up monthly for the first 3 months, and thereafter quarterly. Medication is dispensed on a monthly basis. However, clinical judgment is used to assess whether additional unscheduled visits are required in the interest of patient safety. Specially trained community health care workers and social workers pay home visits for follow up and to monitor the patient’s progress.

Phidisa II is expected to eventually enroll 2800 participants for this study and these persons will be closely monitored not only for the duration of the study, which is expected to run for at least 5 years, but will be managed for the remainder of their lives by SAMHS.

**RESEARCH SITES**

Presently, participants are recruited at five of six investigational base sites and are equally divided into urban and rural/semi rural areas. The five active sites are 1 Military Hospital, Gauteng;
2Military Hospital, Western Cape and Area Military Hospital Unit, Free State; all of which are in urban and well developed areas. The rural sites are Mtubatuba Sickbay, Kwazulu-Natal and

Mthatha Sickbay, Eastern Cape (semi rural). The sixth site is Ba-Phalaborwa Sickbay, Limpopo Province (rural) and is expected to be opened in March/April 2007.

CHECKS AND BALANCES

In order to ensure that all national and international guidelines prescribed for clinical trials in humans are met and even surpassed, strict control mechanisms are in place. These include detailed informed consent, independent national and international monitors, ethical watchdogs such as US Institutional Review Board and the Data Safety and Monitoring Board to monitor any untoward side effects of the medication, ensuring that safety of participants are not compromised.

Pharmaceutical monitoring is indispensable to good quality of care. Phidisa pharmacists ensure the effective and efficient management of pharmaceutical services by amongst other things, ensuring accurate and timely response to all drug related queries, providing patient counseling on the importance of medication adherence and safe sex as well as give general education on the respective antiretrovirals. Innovative ways are also being employed to assist participants by way of, for example, the use of pill boxes.

ADDRESSING APPROPRIATE BROADER ISSUES

Tackling the issue of HIV and AIDS in the military might enhance the de-stigmatisation of the disease and create a culture of encouragement to test for HIV by promoting voluntary counselling and testing (VCT) procedures. It is also hoped that this project might contribute towards creating awareness and a sympathetic understanding and support amongst leaders of people who are ill with the disease. The information obtained from this study might hopefully address and provide recommendations on the best-practise procedures to use when implementing an ARV treatment programme within the Southern African context.

Phidisa is supported by health experts in the management of HIV and AIDS from both national and international organizations. Clinics are staffed by the SANDF as well as civilians medical and other personnel. Staff have regular appropriate training sessions both locally and abroad to ensure that the most relevant and up-to-date knowledge is applied to the project.

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