



CAPRISA

CENTRE FOR THE AIDS PROGRAMME OF
RESEARCH IN SOUTH AFRICA

CAPRISA is supported by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), US Department of Health and Human Services (Grant #151794)

A multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organisation
Registration Number
2002/024027/08

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CAT - CAPRISA AIDS Treatment- project brings hope

The remote rural community of Vulindlela near Howick was once a forgotten region where only the fear of disease and death reigned. Now things are changing with news on the grapevine that medicines available locally will alleviate many of the distressing symptoms of HIV/AIDS

At the CAPRISA research facility in Vulindlela the first three patients given ARVs (through PEPFAR funding) have completed six months of treatment. According to CAPRISA's AIDS Treatment (CAT) Programme clinician Dr T Moodley the initial results have been "encouraging and very inspiring".

In one case – referred to as Patient TM - (ref01) – the CD4 increased from 12 to 186, while viral load decreased from > 66000 to undetectable. In Patient TN - (ref15), the CD4 increased from 130 to 243, and in Patient SS - (ref42) the CD4 increased from 204 to 247.

Dr Moodley said that none of the patients experienced any serious adverse reactions to the medication.

Also encouraging is the level of adherence noted amongst the patients on treatment.

Said Fogarty-Ellison fellow Dan Johnson, who is part of the CAT team at Vulindlela: "We find that patients are keen to learn and have readily accepted the idea of ARVs

as a permanent part of their life.

They do tell us that taking the regimen (mostly five pills a day) has changed their lives and that they are having to think ahead of time to ensure adherence."

To further underpin adherence, patients

are asked to return to the clinic a day or so before their pills run out so that checks can be made on the remaining pills left in the special dated plastic container.

Summing up this new feeling of hope this week was new CAT patient – Daphne – who commenced ARV treatment this month.



**Daphne - a new patient
in the CAT programme**

Daphne who did not object to using her photo or her name for the newsletter (an indication of a more open approach to the disease) said that already she was experiencing benefits.

"I feel so much better with more energy," she said. "Also I am much happier."



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Key team members of the START project who attended a three-day “protocol specific training” workshop in Durban this month.

START: just a few more steps to go

The CAPRISA Starting Tuberculosis and AntiRetroviral Treatment (START) project for patients co-infected with AIDS and TB came a step closer this month with the site initiation visit by the Westat monitoring team.

Now that the green light has been given by the Medicine’s Control Council and ethics committee for the commencement of CAPRISA’s START programme in KwaZulu-Natal, only a few stages are left before the trial begins in earnest.

And if all goes well with the findings of the site initiation visit headed by Doreen Khanye and Diane Pizzano, from Westat’s research programme operations, the way will be clear for the registration of the protocol by the Division of AIDS at at NIH. The WESTAT team also included Cruz Moya.

In preparation for the initiation of this study, a three-day intensive “protocol specific” training workshop was held earlier this month at CAPRISA’s headquarters at the Doris Duke Medical Research Institute.

The entire START team from Durban including core support staff from Data management, Pharmacy, Laboratory, and Administration attended the training.

After welcoming the research team leaders Prof Abdool Karim outlined the key principles of research followed by a broad outline of the START study.

A detailed overview of the informed consent process and the need to avoid all ambiguities was presented by Dr Jerome Singh, head of CAPRISA’s ethics division. START project Director, Dr Kogie Naidoo then discussed the salient elements of the Manual of Operating Procedures (MOP) principles. START clinician Dr Munira Khan presented the protocol for visit logs, checklists and source documentation, while CAPRISA’s protocol pharmacist dealt with study treatment.

Toxicity management is a core element of the study, an issue that was fully aired by consultant clinician Dr Doug Wilson, who also outlined issues involving clinical and study management of AEs and SAEs.

Other topics under discussion included:-

- Schedule of Evaluations and Transition from phase 1 to phase 2 (Dr T Moodley)
- Cohort Retention (Dr N Padayatchi)
- Quality Assurance (Mr R Parathnandh)
- Completion of Case Report Forms (Ms I van Middelkoop)
- Laboratory - specimen collection, forms and labelling, handling and transports (Mr K Coetzee)
- Quality of Life questionnaires (Mr F van Loggerenberg)
- Sexual Behaviour questionnaire (Dr Q Abdool Karim)
- Adherence (Dr K Naidoo)
- Cost effectiveness of integrated and sequential ARV/TB study arm (Ms N Deghaye)
- Questionnaire Completion (Dr N Padayatchi)

The workshop concluded with an interactive discussions on the study of SOP’s and clinical scenarios.

Party time - 70s style

December 2004 was time to have fun after the year's busy schedule. For CAPRISA staff it was a double-decker bus journey to the Gateway's Barnyard Theatre for a few hours of musical enjoyment with the show "Boogie Wonderland" and special festive fare. The 70s theme meant that party goers could dress up in old-fashioned gear, relax and enjoy the nostalgia.

