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NATIONAL

UKZN wins right for ARV trial on babies

Belinda Beresford

09 November 2006 11:59

The University of KwaZulu-Natal (UKZN) has won a high court application for the go-ahead of a clinical trial that will give an anti-retroviral drug to breastfeeding babies, marking another appearance in court for the n-word -- nevirapine.

The researchers, headed by Professor Jerry Coovadia, plan to give nevirapine or a placebo randomly to about 1 100 breastfeeding newborns for a six-month period, to see whether the drug reduces infants' chances of catching HIV.

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Currently, a once-off dose of nevirapine is used to cut the chances of a child becoming infected with HIV during the birth process.

The UKZN team had applied to the Medicines Control Council (MCC) for permission to run the clinical trial, which they hope will prove whether the cheap, one-drug intervention will have a protective effect over a six-month breastfeeding period.

The MCC rejected the application by the UKZN team because of ethical concerns about the placebo arm of the trial, which may put children at risk, and concerns about drug resistance. The researchers then turned to the MCC's appeal committee. This three-person independent committee, which is appointed by the minister of health, overruled the MCC's decision.

The MCC and the researchers then both launched high court applications: the one to deny the authority of the appeal committee and the other to compel the MCC to obey that decision.

This week the university won its case with costs. Lawyer Martin Oosthuizen has asked the MCC to obey that decision and issue the letter of authorisation immediately. The MCC still has a right to appeal and has its own court action pending. The chairperson of the MCC, Professor Peter Eagles, could not be contacted for comment.

The control group of children will be effectively receiving the current prophylactic treatment. There is no proof that nevirapine protects children. Coovadia says the placebo group is of critical importance for the trial because it allows a direct comparison of the nevirapine treatment against no treatment.

This would be the kind of proof required by governments and international agencies to consider including such an intervention in their HIV prevention programmes for children -- if the nevirapine works. "What more appropriate project can we do for the children of Africa? This is a study for Africa and for the poor," he said.

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The principal investigator of the planned trial, Dr Daya Moodley, said that nevirapine would be stopped for any children who became HIV infected to prevent resistance to the drug occurring.

Thousands of children are estimated to become infected with HIV via breastmilk each year. HIV- positive mothers are given the option of free formula milk as a breastmilk substitute, but breastfeeding has been found to be protective for both HIV-positive and HIV-negative babies against disease and malnutrition.

Research into an outbreak of diarrhoeal disease among more than 10 000 children in Botswana earlier this year which killed more than 200 children, found that formula-fed children were more likely to develop diarrhoea and to die regardless of their HIV status.

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