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Thousands more could be treated for HIV in Africa if expensive routine lab tests are dropped

9 December 2009

DART Anti-retroviral Trial – [MRC YouTube channel](#)

A third more people could be successfully treated for HIV in Africa if expensive lab tests routinely used for monitoring side effects are abandoned, according to the 'Development of Anti-Retroviral Therapy in Africa (DART)' clinical trial funded by the Medical Research Council.

Anti-retroviral treatment (ART) is the main type of treatment for HIV or AIDS and involves patients taking drugs every day for the rest of their lives. It is not a cure, but it can stop people from becoming ill for many years. The aim of ART is to keep the amount of HIV in the body at a low level. This helps to stop any weakening of the immune system and allows it to recover from any damage that HIV might have caused already.

In the biggest trial of HIV therapy to date in Africa, published today in *The Lancet*, 3,316 people who had not previously had ART took part. All had severe or advanced HIV infection and had been assessed for ART eligibility using clinical staging and laboratory tests including CD4 cell count (a measure of how well the body's immune system, which is damaged by HIV, is working). The trial began six years ago in Uganda and Zimbabwe when treatment for people with HIV was starting to become more widely available. The report concluded that ART can be delivered safely, without routine laboratory monitoring for toxic effects, but differences in the progression of the disease suggested monitoring CD4-cell count from the second year of treatment. The survival rate in the DART trial is amongst the best reported from any trial, ART programme or study in Africa.

Professor Diana Gibb, co-principal investigator of the study from the Medical Research Council said:

"The survival of people who took part in the trial was remarkable; without treatment only about 10% of HIV-infected African people like those in DART would be expected to survive for five years. In DART, 87% of those receiving treatment without routine blood test monitoring were still alive and well after five years, only 3 percentage points less than in the group that had routine blood test monitoring. For health policy-makers in Africa, DART provides evidence that more people could be treated for the same amount of money by not using routine laboratory tests. This would substantially reduce the number of people dying with serious disease due to HIV infection."

Dr P Mugenyi from co-principal investigator the Joint Clinical Research Centre (JCRC) in Uganda said:

"At least 5 million people still need ART treatment urgently and we know resources are limited. DART results suggest ART can be delivered safely and effectively by trained and supervised health workers in remote communities where routine laboratory services are not available."

Professor James Hakim co-principal investigator from Zimbabwe University said:

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“The evidence from the DART trial will be of value to low income or resource poor countries that are prioritising ART access over investment in expensive laboratory facilities.”

Professor Heiner Grosskurth, co-investigator from the MRC/Uganda Virus Research Institute Uganda Research Unit on AIDS, Entebbe said:

“The DART trial is an example of how working in partnership can deliver excellent results by sharing expertise and resources. Along the way, this collaboration between publically-funded researchers and industry has also helped to develop research capacity in Africa.”

Co-principal investigator Professor Charles Gilks of Imperial College London and now UNAIDS, noted that:

“DART has been a landmark trial in Africa in many ways, not only in the numbers involved and its length, but for the way the patient communities were involved and engaged.”

DART participants were randomly allocated to one of two groups. In one group doctors were given results of regular 3-monthly blood tests to check for ART drug side-effects and measure the CD4 cell count. The second group had the same ART and regular blood tests, but results of safety tests were only given to doctors if they were seriously abnormal and CD4 counts were never seen. People in both groups received free medical care and diagnostic tests for any illness throughout the trial.

The results show that 90% of people having routine lab tests were alive after five years compared to 87% in the group having tests only if clinically needed. 78% and 72% of people in the two groups respectively developed no new AIDS illnesses. These differences appeared to be the result of earlier switching to a different combination of ART in the lab-monitoring group. No difference in the occurrence of side effects caused by ART was found between the two groups.

Ends

Notes to editors:

1. For further information or to arrange an interview with any of the scientist involved in the project, please contact the MRC Press Office on 0207 670 6011 or press.office@headoffice.mrc.ac.uk
2. DART was sponsored and funded by the UK Medical Research Council. Further funding was provided by the UK Department for International Development and the Rockefeller Foundation. Antiretroviral drugs given to trial participants were donated by GlaxoSmithKline, Gilead Sciences, Abbott Laboratories and Boehringer Ingelheim. These pharmaceutical companies also provided funding for some of the sub-studies that were part of the DART trial.
3. For almost 100 years the Medical Research Council has improved the health of people in the UK and around the world by supporting the highest quality science. The MRC invests in world-class scientists. It has produced 29 Nobel Prize winners and sustains a flourishing environment for internationally recognised research. The MRC focuses on making an impact and provides the financial muscle and scientific expertise behind medical breakthroughs, including one of the first antibiotics penicillin, the structure of DNA and the lethal link between smoking and cancer. Today MRC funded scientists tackle research into the major health challenges of the 21st century. www.mrc.ac.uk
4. Scientists and health care workers from Africa and the UK collaborated closely to run the trial. Healthcare and research centres in Uganda were the Joint Clinical Research Centre, Kampala, the Infectious Diseases Institute at Mulago Hospital, Kampala and the MRC/Uganda Virus Research Institute Uganda Research Unit on AIDS, Entebbe. In Zimbabwe, researchers were based at the University of Zimbabwe

Medical School Clinical Research Centre, Harare. The MRC Clinical Trials Unit in London provided overall coordination and the secretariat was provided by the International HIV Clinical Trials Research Management Office at Imperial College London.

5. As the DART trial centres are key centres for ART treatment, most patients are staying at the same clinical centre for their ongoing clinical care, unless for practical reasons they wish to be transferred (e.g. to a health centre nearer to where they live). All participants will continue to receive ART free of charge and most will stay on the same regimen they were taking at the end of the study. All the information from the trial, including all their CD4 results have been summarised for each participant at the end of the trial and shared with the participants and their health carers. Some participants will have the opportunity to enrol in other ART studies if they wish to.

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