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Affordable antibiotic halves the HIV death rate on treatment, DART trial shows

Monday 29 March, 2010

A safe, cheap and widely available antibiotic could save the lives of thousands of people starting anti-retroviral treatment for HIV in Africa and other developing countries. The findings come from a new analysis of the Medical Research Council's (MRC) Developing Antiretroviral Therapy in Africa (DART) trial.

Giving the antibiotic, co-trimoxazole, every day in combination with Anti-Retroviral Therapy (ART) cuts the risk of death by 50 per cent in the first 18 months of treatment - meaning one in two deaths on anti-retroviral treatment were preventable with co-trimoxazole. Antiretroviral therapy itself cuts the risk of death by more than 90%, but cotrimoxazole gives added benefit even on top of this.

Co-trimoxazole (trimethoprim-sulfamethoxazole) is a widely available, low-cost antibiotic that's used in developing countries with limited resources to treat and prevent common infections. In HIV infection, it's highly effective for treating and preventing against pneumonia and *Isospora belli* – a human intestinal disease as well as bacterial infections. The antibiotic has anti-malarial properties and also reduced the occurrence of malaria by 26 per cent.

Dr Sarah Walker, from the Medical Research Council and lead author said:

"The benefits of using this drug are huge, and it's so simple and cost effective to administer. This compelling evidence reinforces the existing World Health Organisation (WHO) guidelines, which have been variably implemented in developing countries. The benefits of this treatment far outweigh the risk of side effects, so healthcare workers can be confident in its effectiveness and help save more lives."

Dr Walker added:

"Working in partnership with international centres of excellence to support global health research is a key focus area for the MRC. The DART trial has been so successful because of the collaboration with partner centres."

Co-author Professor Diana Gibb, from the Medical Research Council said:

"The availability and supply of co-trimoxazole needs to be ramped up. Not just for adults and children waiting to start treatment for HIV, but for everyone starting ART, for at least the first 18 months of treatment. Whether co-trimoxazole can then be stopped after the 72 week period needs further investigation, but there is a significant benefit available now, waiting to be grasped."

DART Principal Investigator, Professor Charles Gilks from Imperial College London added:

"Many patients who start on ART in Africa do so quite late and as a

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consequence have a high risk of dying before treatment starts to be fully effective. Our trial team has unequivocally shown that co-trimoxazole halves mortality in the first 18 months on ART. If physicians and ART centres were to act on the results, and accept that the arguments not to use co-trimoxazole have all been well and truly answered – tens of thousands of lives can be saved by more universal use of the drug, costing just a few pence a day."

WHO guidelines recommend that co-trimoxazole is given to all adult sufferers in developing countries with CD4 counts, which measure the strength of the body's defences, below a certain threshold and should be continued when they start HIV treatment. In wealthier countries, the antibiotic is typically used in combination with ART but discontinued when CD4 count exceeds a set level because the primary goal is to prevent a particularly serious kind of pneumonia.

The observational analysis, which is published in the *Lancet* today, covers 3,179 participants who contributed around four years of follow up each, amounting to more than 14,000 years-worth of follow-up in total. For over half this time the participants were taking co-trimoxazole.

Ends

Notes to Editors:

1. The overall reduction in mortality was 35% - 50% in the first 18 months and then a much smaller effect subsequently, reinforcing the importance of starting co-trimoxazole at the same time as ART.

DART

2. The DART trial was one of the largest ever HIV treatment trials ever carried out in Africa and was subsequently voted runner-up in The Lancet Paper of the Year competition. Visit www.mrc.ac.uk/Newspublications/News for more information on the DART trial.

3. DART was carried out in Uganda and Zimbabwe between 2003 and 2009 and was funded by the Medical Research Council, UK Department for International Development and the Rockefeller Foundation. 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.

4. 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

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For further information or to arrange an interview with any of the scientists involved in the project, please contact the MRC Press Office on 0207 670 6011 or press.office@headoffice.mrc.ac.uk

