International Consortium for Trials of Chemotherapeutic Agents in Tuberculosis (INTERTB)

An international consortium has been created, within the Department of Cellular and Molecular Medicine, to evaluate the clinical and bacteriological outcomes of chemotherapeutic agents for the treatment of tuberculosis.

The consortium, which is a not-for-profit charitable organisation, is responsible for designing, conducting and analyses of randomised controlled clinical trials, to be carried out in countries with a high burden of tuberculosis, through a substantial network of treatment services and laboratories with which relationships already have been established. The primary objective of these trials will be to define regimens of treatment that will have high cure rates and will be simple to administer by the National Tuberculosis Programmes of these countries.

The scientific programme is aimed partly at improvement of current regimens, either by shortening durations of treatment or through the development of intermittent regimens, and partly at assessing new anti-tuberculosis drugs.

Because of their importance in assessing the activity of new anti-tuberculosis drugs, basic studies of factors affecting response to chemotherapy and the study of surrogate markers of relapse will form a major part of the work of the consortium.

In addition, capacity strengthening, to increase the ability of centres to participate in trials, will be an integral part of the consortium's functions.

The Coordinating Centre is based at St. George's, University of London. The International Coordinator, Dr. Amina Jindani, will coordinate all the aspects of the multi-centre trials.

INTERTB has recently been awarded two grants by the European & Developing Countries Clinical Trials Partnership (EDCTP) within the mandate to carry out clinical trials and to strengthen capacity to participate in the trials by the participating centres.

The first grant is for the amount of €4,251,991 for a randomised controlled clinical trial entitled "An international multicentre controlled clinical trial to evaluate high dose rifapentine and a quinolone in the treatment of pulmonary tuberculosis (RIFAQUIN)". The objectives of the trial are to determine whether a treatment regimen containing moxifloxacin substituted for isoniazid in the intensive phase, together with high dose rifapentine, can be administered once weekly in the continuation page and can shorten the duration of the continuation phase with a relapse rate not inferior to a standard control regimen based on rifampicin and isoniazid. Further, whether both test regimens will prevent the occurrence of rifamycin mono-resistance in relapsing HIV positive patients.

The trial, which will be over a period of 4 years, is expected to start enrolling patients after the first quarter on 2007 in 6 participating centres in Mozambique, Zambia, Zimbabwe and South Africa.

The second EDCTP grant is for the amount of €30,000 and is for a workshop to establish a network of sites, in sub-Saharan Africa, to conduct clinical trials in tuberculosis and to build their capacity to participate in multicentre trials.

The workshop will take place at the Unit for Clinical and Biomedical TB Research of the South African Medical Research Council, Durban, South Africa on the 5th, 6th and 7th March, 2007. Participants will come from South Africa, Mozambique, Zambia, Zimbabwe, Nigeria, Republic of Benin and Republic of Guinea.

The workshop agenda will address the following topics:

a. Framing the research question and preparing the protocol
b. Statistical matters such sample size, significance, and power,
c. Study procedures such as randomisation, enrolment, treatment and follow-up.
d. Data management and reporting the results
e. Laboratory procedures relevant to the TB programme's studies
f. Human subjects protection as stipulated by the ICH GCP Guidelines
g. Intellectual property rights.

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