

https://dspace.org/

Analysis of secondary data from Mycobacterium vaccae tuberculosis clinical trial

Mapingure, Munyaradzi Paul

2008-11-04T12:13:27Z
http://hdl.handle.net/10539/5828

Downloaded from a DSpace repository. https://dspace.org/

ANALYSIS OF SECONDARY DATA FROM *Mycobacterium vaccae* TUBERCULOSIS CLINICAL TRIAL

MSc (Medicine) in the field Epidemiology and Biostatistics Research Report

University of the Witwatersrand, Johannesburg 2007

Munyaradzi Paul Mapingure (Student), Jonathan B Levin (Supervisor)

Background: Sputum culture conversion at two months is an important indicator for the effectiveness of treatment and the infectivity of a patient with pulmonary TB. This study aimed at investigating factors that are associated with tuberculosis culture conversion at two months as well as investigating whether sputum culture conversion at two months is a reliable predictor of relapse.

Methods: The study makes use of data obtained from 347 newly diagnosed tuberculosis patients who participated in a randomized placebo controlled immunotherapy trial at King George V hospital in Durban. Above objectives were met by carrying out statistical analysis of the secondary data. Chi-square tests for categorical explanatory variables such as HIV status and smoking status and (b) t-tests for continuous variables such as age were used for investigating factors associated with 2-month culture conversion. Multivariate models were used to find the most important variables for predicting 2-month culture conversion. Kaplan Meier curves were used for investigating whether culture conversion at two months is a reliable predictor of relapse.

Findings: Of the 347 tuberculosis patients, 34 % were HIV sero-positive. Age, body mass index (BMI), smoking status and gender were found to be important variables that affect sputum culture conversion at two moths. At 5 % significance level there was no evidence that those who culture convert at two months were less likely to relapse than those who had not culture converted at two months ($p=0.1165$). However the trend shown is striking to report as it may be of clinical significance. Among those who had not culture converted at two months, more people (40) than expected (34) relapsed an among those who had culture converted at to months, less people (19) than expected (24) relapsed.

Interpretation and recommendations: Some behavioral and biological factors affect two month tuberculosis culture conversion therefore successful tuberculosis management need to take into account the effect of these factors. This study did not show that the sterilizing potential of an anti-tuberculosis regimen can be obtained by evaluation of the culture conversion rates at two months and this may be due to small sample size.