EFFICACY AND SAFETY OF ANTENATAL DEXAMETHASONE IN REDUCING RESPIRATORY DISTRESS AMONG LATE PRETERMS IN MULAGO HOSPITAL:

A RANDOMIZED CONTROLLED TRIAL.

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A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTERS OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY OF MAKERERE UNIVERSITY

MAY 2012

ABSTRACT

Introduction

Late preterm infants, who were previously thought to be as physiologically and metabolically mature as term infants, are now known to be at a higher risk of morbidity and mortality. Respiratory distress is often associated with late preterms than full term infants and its Prevention is of concern. Various investigators have suggested that antenatal treatment with corticosteroids could accelerate lung function in late preterm babies however there is lack of consensus about its use.

General objective

To determine the efficacy and safety of antenatal Dexamethasone in reducing respiratory distress among late preterms in Mulago hospital.

Methods:

This was a double blind randomized controlled trial.

Sixty two women with indication for late preterm delivery were randomly assigned to receive either Dexamethasone or placebo (n = 31).Women in both arms were monitored through labour and delivery and their babies were followed up for 24 hours to look for development of respiratory distress. Babies that required immediate admission to special Care unit post delivery were followed up for a maximum period of 7 days or up to discharge whichever occurred first. Babies delivered vaginally with no feature of distress after 24 hours were discharged then. The post caesarean babies without respiratory distress were followed up to 3days; a time when the mothers were also discharged.

Data was coded and entered into Epidata version 2.1 and exported to STATA version 10.0 for analysis. Analysis was by Intention to treat.

Results

From December 19th, 2011 to April 14th, 2012, out of a total of 351 women who were screened, 62 met the inclusion criteria and were randomly assigned to receive either dexamethasone (n1=31) or placebo (n2=31)

Data on the primary outcome was available for 57 subjects. Babies who developed respiratory distress were 19 (33.3%) including 10(32.2%) in the dexamethasone group and 9(29%) in the placebo arm. Relative risk 1.18 (95% CI 0.63- 2.22) by intention to treat. There were 4 lost to follow up and one intra uterine fetal death.Two babies died due to respiratory distress one in either group. Only one mother who received dexamethasone developed puerperal sepsis. There were no significant differences in the occurrence of adverse events between the two groups.

Conclusions and recommendations

With the available results, there is a high incidence of respiratory distress among late preterms (33.3%), and no benefit of antenatal dexamethasone in reducing it. There is need therefore to establish the particular cause of respiratory distress in this group. Further studies on the molecular and genetic pathology of respiratory distress in late preterms could direct future therapies. The study is ongoing to complete the sample size.