

Misoprostol in Addition to Routine Management of Postpartum Hemorrhage: A Hospital-Based Randomized Controlled Trial in Karachi

Summary of Research

Introduction

Postpartum hemorrhage (PPH) remains a leading cause of maternal mortality worldwide, despite treatment with conventional uterotonics. A woman suffering from excessive bleeding after childbirth can die quickly unless she receives immediate and appropriate medical care. A crucial component in the treatment of PPH is the administration of injectable uterotonics. The postpartum administration of misoprostol has also recently entered into clinical practice for the treatment of PPH. Misoprostol offers several important advantages over standard PPH treatments, including its oral administration, stability at high temperatures, no contraindication to hypertensive patients, wide availability, and low cost. Several reports have suggested that misoprostol may be a powerful treatment for PPH both when used alone and in conjunction with standard uterotonics, however no standard regimens or protocols have been developed. The Aga Khan University, Aga Khan Health Services-, and Gynuity Health Projects are jointly conducting a double-blinded randomized-controlled trial to determine the effectiveness of 600mcg sublingual misoprostol as an adjunct treatment to standard PPH care (injectable oxytocin with or without ergometrine) at four hospitals in Karachi.

Study Description

The purpose of the trial is to ascertain whether misoprostol, in addition to standard injectable uterotonics, is more effective than a regimen of oxytocin in stopping hemorrhage. Consenting women will receive standard management for PPH with an additional treatment of either 600mcg sublingual misoprostol or matching placebo. Women with cesarean-section, a gestational age of less than 28 weeks, postpartum blood loss <500mls, or postpartum bleeding not due to uterine atony are not eligible for the trial. The primary outcome is measured blood loss • 500mls after receiving study treatment; secondary outcomes include change in hemoglobin, side effects, clinical complications, and mean blood loss. As of December 2005, data collection is ongoing at the following hospitals: The Aga Khan University Hospital, Aga Khan Hospital for Women in Karimabad, Aga Khan Hospital for Women in Garden, and Aga Khan Hospital for Women and Children in Kharadar.

The trial has a pragmatic approach with minimal interference or change in the current routine management of delivery at the participating hospitals. All women will undergo routine active management of the third stage of labor with standard uterotonics. Immediately after delivery, consenting women will have their blood loss collected – placing a fracture bedpan directly under the woman – for a minimum of one hour and until active bleeding ceases. If measured blood loss after delivery is • 500mls, routine PPH treatment and the study treatment are provided, at which time blood collection is restarted. The results from this study promise to provide an important contribution to the medical community's understanding of the variation of PPH rates in hospital settings, and the characteristics of PPH in Pakistan, in particular. Furthermore, this study will bolster documentation on the safety of 600mcg sublingual misoprostol, the use of the bedpan for standardized blood collection, and standardized hospital care in PPH management.

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