

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/ 2014/010

Scientific title of trial: Prophylactic use of antibiotic (doxycycline) for incomplete and missed miscarriage, prior to medical and surgical management

Date of commencement (enrolment of first participant): 26/05/2014

Progression: 6 months 1 year 2 years 3 years

At completion x

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: No

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: pending/ recruiting/ recruitment complete/ recruitment suspended / recruitment terminated

Number assessed for eligibility:

Number recruited and randomized: 394

Number allocated to each intervention/arm: Group A – 200 (Doxycycline arm)
Group B - 194 (placebo arm)

Losses/exclusions after randomization: 16 were lost at two weeks follow up
07 in Group A & 09 in Group B

3. Trial output

Summary of Interim/Final data (if available):

Result:

Statistically significant difference was not detected regard to age, parity, number of children and POA in between the doxycycline and placebo groups. Post intervention pelvic infection was diagnose 4% and 6.18% respectively in the doxycycline group and the placebo group within three days, which was not statistically significant (P= 0.367). It was 4.5% and 8.7% for doxycycline and placebo treated groups respectively at two weeks. It was also not clinically significant (P=0.104). Statistically significant difference was not detected in regard to type of miscarriage or type of interventions in between the two groups

(Please attach a scanned copy or link to abstract)

Abstract

Introduction

Loss of a pregnancy prior to achieve viability is defined as a miscarriage. It is a common gynaecological problem which we encountered day today practice. Post miscarriage care is a challenging area coming under reproductive health. It is recognized internationally as an important component of reproductive health to address complications of miscarriage. Prevention of pelvic sepsis is a main component in post miscarriage care. Effective antibiotic prophylaxis prior to management of for incomplete & missed miscarriage may be the answer for it. But in current practice, there is conflicting evidence and no clear guidance regarding the necessity of the antibiotic prophylaxis.

Objective :

To determine the effectiveness of prophylactic doxycycline use, prior to surgical and medical management of incomplete and missed miscarriage, in view of reducing the post-operative pelvic infections.

Design :

A randomized controlled trial

Setting:

Professorial Gynaecology Unit, Teaching Hospital, Peradeniya, Sri Lanka.

Method :

Three hundred and ninety four patients randomized to two groups to received doxycycline or placebo. Single dose of doxycycline 200mg to one group and single dose of placebo to other group had given one hour prior to the medical and surgical management of miscarriage. Post procedure pelvic infection was assessed by five clinical parameters within three days (before

discharge) and two weeks later at the clinic setting. Data analysis was done by using Statistical Package for the Social Sciences (SPSS) version 20.

Result:

Statistically significant difference was not detected regard to age, parity, number of children and POA in between the doxycycline and placebo groups. Post intervention pelvic infection was diagnose 4% and 6.18% respectively in the doxycycline group and the placebo group within three days, which was not statistically significant (P= 0.367). It was 4.5% and 8.7% for doxycycline and placebo treated groups respectively at two weeks. It was also not clinically significant (P=0.104). Statistically significant difference was not detected in regard to type of miscarriage or type of interventions in between the two groups.

Conclusion:

The study revealed that antibiotic prophylaxis prior to medical and surgical management of miscarriage was unable to obtain a statistically significant reduction in post intervention pelvic infection.

Publications: Still not
(Please attach a scanned copy or link to paper)

D.P.G.G.M. Prasanga
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Name and signature of Responsible Registrant/

Date: 12/10/ 2016