Protecting Pregnant women from malaria: exploring safety data

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Defeating Malaria Together
• Indonesia is the first country to introduce DP for treatment of malaria.
• It became policy in March 2006—changed from CQ-SP.
• Same time for treatment of 2\textsuperscript{nd} & 3\textsuperscript{rd} trimester pregnancy & infants.
• Data available electronically in the hospital.
DHP exposure

March 2006
Safety of artemesinins in first trimester—what is known

• Malaria in 1\textsuperscript{st} trimester is known to be associated with pregnancy loss (miscarriage or stillbirth)
• ACTs more effective than quinine, well tolerated and already widely used in 1\textsuperscript{st} trimester
• Quinine is not well tolerated and poor compliance to 7 day treatment $\rightarrow$ untreated malaria
• Safety data is limited but doesn’t indicate any safety signal with artemisinins in humans
• 90\% of ACT safety data comes from artemether-lumefantarine
First Trimester DHP exposure study

• **Rationale:**
  • Has a computerized recording system in the hospitals
  • Larger database at our disposal for data abstraction
  • Infrastructure and trained staff experienced in obtaining data in place
  • An extension of existing collaboration between Timika research facility and LSTM
Objectives

• Compare the risk of miscarriage and stillbirths between women treated with DHP and quinine in 1st trimester
• Compare the risk of congenital anomalies in between women treated with DHP and quinine in 1st trimester
• Secondary: assess maternal, fetal and infant morbidity and mortality outcomes during 8 weeks post-natal period
Study design

• Observational record linkage retrospective & prospective component

• **Sample size:**
  • Retrospective: 1500 exposures (225 DHP & 1245 quinine)
  • Prospective: 298 women (50 DHP, 248 quinine (inadvertent))
Retrospective cohort-record linkage

**Exposure**
- quinine
- DP
- none

**Data source**
- emergency
- delivery
- pharmacy
- inpatient

**Outcome**
- Miscarriage
- Stillbirth
- Congenital anomalies
Prospective cohort

Eligibility criteria
- Check gestational age by U/S: < 24 weeks
- Confirm malaria/fever history (recall), treatment –past 6 months
- Check medical records for treatment: DP/quinine

Follow-up antenatal visit
- Fetal viability
- h/o fever, malaria
- Drug treatment

Delivery & post natal
- Term/preterm
- Baby: surface examination for congenital anomalies
- Birth weight
Outcomes of study

• Expected to add to existing safety data

• **Pregnant women**: miscarriage and stillbirths

• **Newborns**: surface congenital anomalies, preterm birth (babies)

• **Post-natal**: maternal and infant morbidity and mortality upto 6-8 weeks
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