IST or IPT with DHP versus SST in Pregnancy in Indonesia: Results

Malaria In Pregnancy-APMEN Meeting
Denpasar, 10 October 2017

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Is **IPT** better than **SST** and **IST**?

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Conclusions

• IPT is better than SST (but only in Papua)
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• IST is not better than SST (Sumba and Papua) because it did not detect more infections than SST
  – Only 5 RDT+ out of 2,886 screening visits in IST arm (a total of 18 cases detected by RDT)
  – More infections detected and treated in SST arm during follow-up (passive case detection), despite monthly screening with RDT in IST arm
  – Majority of infections were RDT+ subpatent (Pf 78%; Pv 89%)
IPT with DHP:
Birth Weight, Cardiac Safety, Tolerability
Summary ECG findings  
(n=33, IPT arm only)

• Mean (SD) prolongation:
  – QTcF: 20ms (20) (range -20 to 71)
  – QTcB: 15ms (18) (range -25 to 63)

• No clinical cardiac adverse events.

• No evidence that the QTc prolongation increases with successive number of monthly courses of DHP
Tolerance

Early vomiting rates: <1%
Tolerance improved after subsequent doses

<table>
<thead>
<tr>
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<th>Enrollment (n=674)</th>
<th>ANC1 (n=591)</th>
<th>ANC2 (n=440)</th>
<th>ANC3 (n=247)</th>
<th>ANC4 (n=88)</th>
<th>ANC5 (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vomiting</td>
<td>7% (45)</td>
<td>4% (25)</td>
<td>2% (10)</td>
<td>2% (5)</td>
<td>2% (2)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Nausea</td>
<td>4% (26)</td>
<td>3% (19)</td>
<td>3% (13)</td>
<td>1% (3)</td>
<td>2% (2)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Headache</td>
<td>5% (33)</td>
<td>3% (16)</td>
<td>2% (8)</td>
<td>4% (9)</td>
<td>2% (2)</td>
<td>0% (0)</td>
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</tbody>
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Adherence

87% took all 3 doses and each scheduled course
High drop out due to refusals in IPT group in Papua (Rumours, antimalarial for healthy pregnant woman)
Limitations

• Cluster randomized and open label design: Prone to differences at base line
  – 43% lower prevalence of malaria at enrolment in IST arm
  – Malaria prevalence at enrolment strong predictor of malaria at delivery: confounded the IST vs SST and IST vs IPT comparison in favour of IST

• 82% women contributed to primary endpoint: relatively low
  – Half of the non-contributors were due to refusals (consent withdrawals)
  – Significantly higher in the IPT arm than other arms (mostly in Papua)
Conclusions

• Majority of infections were below the level of RDT or microscopy detection and asymptomatic
• Clinical malaria was rare, also in SST arm (1.5%)

• IST
  – Monthly screening with the current generation of RDTs unlikely to be ever cost-effective
  – More studies are needed with highly sensitive RDTs

• IPT: Monthly 3 day DHP
  – Potential alternative to SST strategy in Papua Indonesia and other areas with moderate transmission in the Asia-Pacific region
  – Implementation study: determine feasibility and strategy of a new concept of preventive treatment in pregnancy
Acknowledgments

STOPMIP Investigators

- Feiko ter Kuille
- Rukhsana Ahmed
- Jeanne Rini Poespoprodjo
- Din Syafruddin
- Carole Khairallah
- Cheryl Pace
- Theda Lukito
- Silvia Maratina
- Puji Asih
- Maria Santana-MoraLes
- Emily Adams
- Vera Unwin
- Chris Williams
- James Smedley
- Tao Chen
- Duolao Wang
- Brian Faragher
- Ric Price

- **DMEC members:**
  - Andy Stergachis
  - Tim Peto
  - Marcus Rijken

- **TSC members:**
  - Bill Hawley
  - Larry Slutsker
  - Julie Simpson,
  - Rosemary Keogh
  - Padma Murti

- **Officials:** DHO, Puskesmas & Posyandu staff, Village Heads and village community

- **LSTM Governance**

- **Prodia CRO**

Papua Networks:

- Mimika District Government
- Malaria Control PTFI
- LPMAK
- RSUD Mimika and RSMM
- YPKMP

**Study participants:** Pregnant women and babies
Acknowledgments

- **Funder:** United Kingdom Joint Global Health Trials Scheme (JGHT: G100024)

Cardiac monitoring  LAMP kits  Study drug
Special Thanks to the Field Teams:

**Sumba:** Sheria Puspita Arum, Nenci Siagian, Melinda Soemarno, Irvin Romyco Andre Pawira Putra, Muhammed Takbir, Ismail Ekoprayitno Rozi, Nanda Rizky Pratama, Wirda Damanik, Suradi Wangsamuda, Wajio Sumarto

**Timika:** Faustina Helena Burdam; Enny Kenangalem; Argo Pambudi; Fanny Kamarudy Lay; Freis Candrawati, Prayoga Ambarawa, Leily Triyanti and Rintis Noviyanti.

Nurse/midwives, site office administrators, home visitors, study drivers and data entry clerks in both sites