



Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM COMBI

Scientific Title Cotrimoxazole for Mothers to improve birth weight in infants

Primary Sponsor Details

Sponsors * Zvitambo

Secondary Sponsor Details

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Affiliation University of Zimbabwe

Countries of Recruitment *

Zimbabwe

Source of Funds MRC UK, WELCOME TRUST

Health Condition(s) or Problem(s) Studied * This is a proof-of-concept trial designed to evaluate whether cotrimoxazole prophylaxis during pregnancy improves birth weight by reducing SGA and preterm birth.

Medicine Name * Cotrimoxazole

Quantity of medicine required * Daily dose of 960mg of cotrimoxazole in two tablets, each 480g

7.0 PRINCIPAL INCLUSION CRITERIA *

Women must meet all of the following inclusion criteria:

- Confirmed pregnant
- Known HIV status in the current pregnancy
- Willing to receive all their antenatal care at one of the study clinics

7.1 PRINCIPAL EXCLUSION CRITERIA *

None of the following exclusion criteria must be met:

- Currently receiving or eligible to receive cotrimoxazole prophylaxis^a
- Contraindication to cotrimoxazole^b
- Any other acute or chronic condition that might interfere with the study, as judged by the research clinician^c

7.2 PRIMARY END POINTS *

Infant birth weight.

9.0 DESIGN OF THE TRIAL

Type of trial * Controlled

If controlled

Randomised Yes

Single Blind No

Double Blind Yes

Parallel group No

Cross over No

Other No

If yes to other, specify

If controlled, specify the comparator

Other medicinal product(s) No

Placebo Yes

Other No

If yes to other, specify

Other No

Expected Number of participants in Zimbabwe *	1000
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	1000
Total participants worldwide *	1000

Time period for the trial * 24 Months