

Screening and treatment of malaria in pregnancy in West Africa

Alternative Title

A non-inferiority, individually randomized trial of intermittent screening and treatment versus intermittent preventive treatment in the control of malaria in pregnancy

Data Creators

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Abstract

The efficacy of intermittent preventive treatment for malaria with sulfadoxine-pyrimethamine (IPTp-SP) in pregnancy is threatened in parts of Africa by the emergence and spread of resistance to SP. Intermittent screening with a rapid diagnostic test (RDT) and treatment of positive women (ISTp) is an alternative approach.

Methods

The study conducted an open, individually randomized, non-inferiority trial of IPTp-SP versus ISTp in 5,354 primi- or secundigravidae in The Gambia, Mali, Burkina Faso and Ghana. Despite the low prevalence of resistance to SP in these countries, ISTp-AL was non-inferior to IPTp-SP in preventing low birth weight (LBW), anemia and placental malaria at the primary trial endpoints. More women in the ISTp-AL than in the IPTp-SP group presented with malaria parasitemia between routine antenatal clinics, but the number of hospital admissions for malaria was similar in the two groups. In the absence of an effective alternative medication to SP for IPTp, ISTp-AL is a potential alternative to IPTp in areas where SP resistance is high. It may also have a role in areas where malaria transmission is low and for the prevention of malaria in HIV positive women receiving cotrimoxazole prophylaxis in whom SP is contraindicated.

Spatial Coverage:

Data was collected in The Gambia, Mali, Burkina Faso and Ghana

Temporal Coverage:

Data was collected between 2010 – 2012 and locked for analysis during 2013 (clinical findings) and 2014 (laboratory findings). Data held within this collection was prepared in 2015.

Quality Controls

A Data and Safety Monitoring Board (DSMB) at the London School of Hygiene & Tropical Medicine reviewed the overall conduct of the trial and approved the analytical plans. The trial was monitored by independent clinical monitors.

Species:

Human population

Privacy:

The datasets have been anonymised to remove personal identifiers. However, using information on timing of clinic visits, demographic details etc. it may be possible for individuals to be identified in the database, including by the participants themselves (self-identification). For this reason, access to the dataset is controlled. Requests for access to the data should be made using the data request form in LSHTM Data Compass.

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Ethics

The trial protocol and amendments were approved by the ethics committees of each of the participating African centers and by the ethics committee of the London School of Hygiene & Tropical Medicine (table 2 in supplementary tables of the published paper).

Keywords

Malaria, Pregnancy, Intermittent Preventive Treatment in Pregnancy, Intermittent Screening and Treatment in Pregnancy, IPTp, ISTp

Project Information

Project

Data generated as part of Intermittent Preventive Treatment with Sulfadoxine-Pyrimethamine Versus Intermittent Screening and Treatment of Malaria in Pregnancy in West Africa (IPTp-SP vs. ISTp) trial. See <https://clinicaltrials.gov/ct2/show/NCT01084213> for details.

Funder/Sponsor

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Data Collection Description

Title	Filename	File type	Description
Main study file	1_main_study_file.dta	Stata Data File	<p>The dataset contains 5354 records, each of which relates to a study participant (a primi- or secundi-gravid pregnant woman enrolled in one of the study centres in Burkina Faso, the Gambia, Ghana or Mali).</p> <p>Information in the database includes:</p> <ul style="list-style-type: none"> • information on demographic factors • obstetric information • information on interventions received • information obtained at different ANC visits during the study period • details of the outcomes of pregnancy <p>The dataset can be used to verify all results outlined in the associated paper and supplement, with the exception of those shown in the other files listed in this table (congenital abnormalities, and results related to unscheduled illness visits).</p>
	1_main_study_file.csv	Comma Separated Values	CSV version of the above file
	1_data_dictionary_main_study_file.docx	Microsoft Word Document	Data Dictionary, variable names, codes, units of measurement
Congenital abnormalities	2_congenital_abnormalities.dta	Stata Data File	This dataset shows the reported congenital abnormalities by study ID and study group. The 5321 individuals with no ca_details are those without a congenital abnormality. Variables are labelled in the Stata file, and further details are given in the corresponding data dictionary file.
	2_congenital_abnormalities.csv	Comma Separated Values	CSV version of the above file
	2_data_dictionary_congenital_abnormalities.docx	Microsoft Word	Data Dictionary, variable names, codes, units of measurement
Unscheduled clinic visits	3_illness_file_long_for_archive.dta	Stata Data File	This dataset contains records of each illness visit. Women who experienced multiple illness episodes are listed in an equivalent number of records.

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			The dummy variable illvisit indicates illness episodes: if equal to 1, the record reports an illness episode, if not equal to one (missing) the woman listed did not have an unscheduled illness visit during the study.
	3_illness_file_long_for_archive.csv	Comma Separated Values	.csv version of the above file.
	3_illness_file_single_record_per_subject_for_archive.dta		Unscheduled illness visits arranged as a single record per woman, to allow tabulation of number of visits per woman by study group, etc.
	3_illness_file_single_record_per_subject_for_archive.csv		CSV version of the above file
	3_data_dictionary_unscheduled_illness_visits.docx	Word Document	Data Dictionary, variable names, codes, units of measurement
Symptoms at unscheduled visits	4_symptoms_at_illness_episodes_LONG_for_archive.dta	Stata Data File	Dataset contains a breakdown of the common symptoms experienced at the time of illness visits. Each record denotes a single illness visit. Women who experienced more than one illness episode are listed in multiple records. The dummy variable illvisit indicates illness episodes: if equal to 1, the record reports an illness episode, if not equal to one (missing) the woman listed did not have an unscheduled illness visit during the study.
	4_symptoms_at_illness_episodes_LONG_for_archive.csv	Comma Separated Values	CSV version of the above file.
	4_data_dictionary_symptoms_at_unscheduled_illness_visits.docx	Word Document	Data Dictionary, variable names, codes, units of measurement