Clinical trial results:
Phase 3, Open-Label, Randomized, Comparative Study to Evaluate Azithromycin plus Chloroquine and Sulfadoxine plus Pyrimethamine Combinations for Intermittent Preventive Treatment of Falciparum Malaria Infection in Pregnant Women in Africa

Summary

EudraCT number	2014-004952-80
Trial protocol	Outside EU/EEA
Global end of trial date	08 November 2013

Results information

Result version number	v1
This version publication date	23 May 2016
First version publication date	31 July 2015

Trial information

Trial identification

Sponsor protocol code	A0661158

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01103063
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Clinical Trials.gov Call Center, Pfizer Inc, 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Clinical Trials.gov Call Center, Pfizer Inc, 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 September 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 November 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To establish superiority of azithromycin/chloroquine (AZCQ) over sulfadoxine-pyrimethamine (SP) in protective efficacy for intermittent preventive treatment in pregnancy (IPTp) as measured by the proportion of subjects with sub-optimal pregnancy outcome.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 October 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	1 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Malawi: 611
Country: Number of subjects enrolled	Benin: 62
Country: Number of subjects enrolled	Tanzania, United Republic of: 839
Country: Number of subjects enrolled	Kenya: 1029
Country: Number of subjects enrolled	Uganda: 350
Worldwide total number of subjects	2891
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	142
Adults (18-64 years)	2749
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This Phase 3, open label, randomized, parallel group study screened a total of 3259 subjects in 6 sites. A total of 2891 were treated either with azithromycin+chloroquine or sulfadoxine+pyrimethamine.

Pre-assignment

Screening details:

Pregnant women (all gravidae) with greater than equal to (≥) 14 and less than equal to (≤) 26 weeks of gestational age were to be enrolled in this study. Approximately half of the subjects were to be primigravidae and secundigravidae pregnant women since they had a higher risk for suboptimal pregnancy outcomes due to malaria.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Azithromycin + Chloroquine

Arm description:

The subjects received Azithromycin (AZ) and Chloroquine (CQ) base by mouth once daily for 3 days (Days 0, 1, 2) per treatment. There were a total of 3 treatments at 4-8 week intervals.

Arm type	Experimental
Investigational medicinal product name	Azithromycin + Chloroquine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Azithromycin (AZ) and Chloroquine (CQ) was administered orally at a dose of 1000 mg AZ and 620 mg CQ (4 combination tablets of AZCQ with individual strength of 250 mg/155 mg), once daily for 3 days (Days 0, 1, 2) per treatment.

Arm title	Sulfadoxine + Pyrimethamine

Arm description:

The subjects received sulfadoxine-pyrimethamine (SP) (Fansidar) single oral dose on Day 0 of each treatment. There were a total of 3 treatments at 4-8 week intervals.

Arm type	Active comparator
Investigational medicinal product name	Sulfadoxine + Pyrimethamine
Investigational medicinal product code	
Other name	Fansidar
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Sulfadoxine-Pyrimethamine (SP) (Fansidar) was administered orally at a dose of 1500 mg sulfadoxine and 75 mg pyrimethamine (3 fixed tablets of SP strength at 500 mg/25 mg) on Day 0 of each treatment.

Number of subjects in period 1	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine
Started	1446	1445
Completed	969	1024
Not completed	477	421
Consent withdrawn by subject	60	15
Study terminated by Sponsor	326	342
Death	3	1
Not specified	16	11
'Adverse Event '	3	1
Protocol Violation	1	-
Lost to follow-up	68	51

Baseline characteristics

Reporting groups	
Reporting group title	Azithromycin + Chloroquine
Reporting group description:	
The subjects received Azithromycin (AZ) and Chloroquine (CQ) base by mouth once daily for 3 days (Days 0, 1, 2) per treatment. There were a total of 3 treatments at 4-8 week intervals.	
Reporting group title	Sulfadoxine + Pyrimethamine
Reporting group description:	
The subjects received sulfadoxine-pyrimethamine (SP) (Fansidar) single oral dose on Day 0 of each treatment. There were a total of 3 treatments at 4-8 week intervals.	

Reporting group values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine	Total
Number of subjects	1446	1445	2891
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	23.3	23.3	
standard deviation	± 4.5	± 4.6	-
Gender categorical			
Units: Subjects			
Female	1446	1445	2891
Male	0	0	0

End points

End points reporting groups

Reporting group title	Azithromycin + Chloroquine
Reporting group description:	
The subjects received Azithromycin (AZ) and Chloroquine (CQ) base by mouth once daily for 3 days (Days 0, 1, 2) per treatment. There were a total of 3 treatments at 4-8 week intervals.	
Reporting group title	Sulfadoxine + Pyrimethamine
Reporting group description:	
The subjects received sulfadoxine-pyrimethamine (SP) (Fansidar) single oral dose on Day 0 of each treatment. There were a total of 3 treatments at 4-8 week intervals.	

Primary: Percentage Subjects With Sub-optimal Pregnancy Outcome in Intent-to-Treat (IIT) Population

End point title	Percentage Subjects With Sub-optimal Pregnancy Outcome in Intent-to-Treat (IIT) Population
End point description:	
Adverse pregnancy outcomes were defined as live-borne neonate (singleton) with low birth weight (LBW) (less than (<)2,500 g), premature births (<37 weeks as confirmed by the Ballard score), abortion (less than equal to (≤)28 weeks), still birth (greater than (>)28 weeks), lost to follow-up prior to termination of pregnancy or delivery, or missing birth weight of the neonates. Intent To Treat (ITT) set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.	
End point type	Primary
End point timeframe:	
Approximately 40 weeks of gestational age	

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1445	1445		
Units: Percentage of subjects				
number (confidence interval 95%)	26.16 (23.89 to 28.43)	23.67 (21.48 to 25.86)		

Statistical analyses

Statistical analysis title	Sub-optimal Pregnancy in ITT Population
Statistical analysis description:	
Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.	
Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2890
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.12237
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.25
Variability estimate	Standard deviation
Dispersion value	0.0647

Secondary: Percentage of Subjects With Sub-optimal Pregnancy Outcome in Efficacy Analyzable Per Protocol (PP) Population

End point title	Percentage of Subjects With Sub-optimal Pregnancy Outcome in Efficacy Analyzable Per Protocol (PP) Population

End point description:

Adverse pregnancy outcomes were defined as live-borne neonate (singleton) with LBW (<2,500g), premature births (<37 weeks as confirmed by the Ballard score), abortion (≤28 weeks), still birth (>28 weeks), lost to follow-up prior to termination of pregnancy or delivery, or missing birth weight of the neonates. Subset of ITT subjects: outcome or withdrawal occurred on or before 8/27/2013 (date of study termination), compliant with study medication, birth weight measured on or before 7 days after birth if not already a failure, and did not switch to standard of care.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1089	1176		
Units: percentage of Psubjects				
number (confidence interval 95%)	10.38 (8.57 to 12.19)	10.12 (8.4 to 11.84)		

Statistical analyses

Statistical analysis title	Sub-optimal Pregnancy Efficacy in PP Population

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2265
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.84117
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.31
Variability estimate	Standard deviation
Dispersion value	0.1243

Secondary: Percentage of Neonates With LBW (<2500 g) in ITT Population

End point title	Percentage of Neonates With LBW (<2500 g) in ITT Population

End point description:

LBW was defined as live birth weight <2500 g (up to and including 2499 g). ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1140[1]	1190[2]		
Units: percentage of neonates				
number (confidence interval 95%)	5.01 (3.74 to 6.28)	5.72 (4.4 to 7.04)		

Notes:

[1] - N=Total live births.

[2] - N=Total live births.

Statistical analyses

Statistical analysis title	LBW in ITT Population

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4428
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.23
Variability estimate	Standard deviation
Dispersion value	0.1745

Secondary: Percentage of Neonates With LBW (<2500 g) in Efficacy Analyzable PP Population

End point title	Percentage of Neonates With LBW (<2500 g) in Efficacy Analyzable PP Population

End point description:

LBW was defined as live birth weight <2500 g (up to and including 2499 g). Subset of ITT subjects: outcome or withdrawal occurred on or before 8/27/2013 (date of study termination), compliant with study medication, birth weight measured on or before 7 days after birth if not already a failure, and did not switch to standard of care.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1041[3]	1134[4]		
Units: percentage of neonates				
number (confidence interval 95%)	4.72 (3.43 to 6.01)	5.21 (3.92 to 6.5)		

Notes:

[3] - N=Total Live Births.

[4] - N=Total Live Births.

Statistical analyses

Statistical analysis title	LBW in PP Population

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2175
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6086
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.31
Variability estimate	Standard deviation
Dispersion value	0.1882

Secondary: Percentage of Subjects With Severe Maternal Anemia (Hemoglobin [Hb] <8 g/dL) at 36-38 Weeks of Gestation

End point title	Percentage of Subjects With Severe Maternal Anemia (Hemoglobin [Hb] <8 g/dL) at 36-38 Weeks of Gestation

End point description:

Severe maternal anemia was defined as Hb <8 gram per decilite (g/dL). ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

At 36-38 weeks of gestation

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1222[5]	1299[6]		
Units: percentage of subjects				
number (confidence interval 95%)	1.08 (1.05 to 2.55)	2 (1.24 to 2.76)		

Notes:

[5] - N=Number of subjects with Hb measurement at 36-38 weeks gestation.

[6] - N=Number of subjects with Hb measurement at 36-38 weeks gestation.

Statistical analyses

Statistical analysis title	Severe Maternal Anemia at 36-38 Weeks
Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2521
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	= 0.7035
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.57
Variability estimate	Standard deviation
Dispersion value	0.2866

Notes:

[7] - Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Secondary: Percentage of Subjects With Maternal Anemia (Hb <11 g/dL) at 36-38 Weeks of Gestation

End point title	Percentage of Subjects With Maternal Anemia (Hb <11 g/dL) at 36-38 Weeks of Gestation

End point description:

Anemia was defined as Hb <11 g/dL. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

At 36-38 weeks of gestation.

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1222[8]	1299[9]		
Units: percentage of subjects				
number (confidence interval 95%)	50.57 (47.77 to 53.37)	49.11 (46.39 to 51.83)		

Notes:

[8] - N=Number of subjects with Hb measurement at 36-38 weeks gestation.

[9] - N=Number of subjects with Hb measurement at 36-38 weeks gestation.

Statistical analyses

Statistical analysis title	Maternal Anemia at 36-38 Weeks

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine
Number of subjects included in analysis	2521
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4605
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.11
Variability estimate	Standard deviation
Dispersion value	0.04

Secondary: Percentage of Subjects With Placental Parasitemia at Delivery

End point title	Percentage of Subjects With Placental Parasitemia at Delivery

End point description:

Subjects with placental parasitemia at delivery were diagnosed using Placental blood smear at birth from subjects who deliver at hospital. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age.

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1019[10]	1076[11]		
Units: percentage of subjects				
number (confidence interval 95%)	5.3 (3.92 to 6.67)	5.67 (4.29 to 7.05)		

Notes:

[10] - N=Number of subjects with placental parasite counts at delivery.

[11] - N=Number of subjects with placental parasite counts at delivery.

Statistical analyses

Statistical analysis title	Placental Parasitemia Delivery

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2095
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7105
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.33
Variability estimate	Standard deviation
Dispersion value	0.1817

Secondary: Percentage of Subjects With Placental Malaria at Delivery Based on Histology

End point title	Percentage of Subjects With Placental Malaria at Delivery Based on Histology

End point description:

Subjects positive for placental malaria at delivery were evaluated based on placental histology. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1040[12]	1100[13]		
Units: percentage of subjects				
number (confidence interval 95%)	4.81 (3.51 to 6.11)	5.73 (4.36 to 7.1)		

Notes:

[12] - N=Number of subjects with a histology parasite evaluation at delivery.

[13] - N=Number of subjects with a histology parasite evaluation at delivery.

Statistical analyses

Statistical analysis title	Placental Malaria

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2140
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3468
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	1.21
Variability estimate	Standard deviation
Dispersion value	0.1842

Secondary: Sexually Transmitted Infection (STI) Episodes Per Subject

End point title	Sexually Transmitted Infection (STI) Episodes Per Subject

End point description:

Number of episodes of sexually transmitted infection episodes per subjects were noted. The STI's including Treponema pallidum, Neisseria gonorrhoeae, Chlamydia trachomatis, from first dose to delivery (diagnosis was based on clinical presentation and lab results). ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1445[14]	1445[15]		
Units: number of episodes				
least squares mean (confidence interval 95%)	0.14 (0.11 to 0.16)	0.19 (0.17 to 0.21)		

Notes:

[14] - N=Number of subjects with available data.

[15] - N=Number of subjects with available data.

Statistical analyses

Statistical analysis title	STI Episodes Per Subjects

Statistical analysis description:

Analysis based on an ANOVA model with model terms for treatment group and randomization stratification variable. A negative mean difference between treatment groups favors Azithromycin + Chloroquine (reduction in number of STIs). The 2-sided P-value tests the null hypothesis that the mean difference is 0 (treatment group equality) versus not equal 0.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2890
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0011
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.08
upper limit	-0.02
Variability estimate	Standard error of the mean
Dispersion value	0.02

Secondary: Percentage of Subjects With Sub-optimal Pregnancy Outcome Including Neonatal Death and Congenital Malformation

End point title	Percentage of Subjects With Sub-optimal Pregnancy Outcome Including Neonatal Death and Congenital Malformation

End point description:

Sub-optimal pregnancy outcome including neonatal deaths and congenital malformations, defined as any of the following: live-borne neonate (singleton) with low birth-weight (or LBW for short, defined as live birth weight <2,500g), premature birth (<37 weeks), abortion (≤28 weeks), still birth (>28 weeks), ND, CM, lost to follow-up prior to termination of pregnancy or delivery, or missing birth weight of the neonates. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1445[16]	1445[17]		
Units: percentage of subjects				
number (confidence interval 95%)	28.51 (26.18 to 30.84)	26.51 (24.23 to 28.79)		

Notes:

[16] - N=Total Outcomes.

[17] - N=Total Outcomes.

Statistical analyses

Statistical analysis title	Sub-optimal Pregnancy:neonatal death, malformation

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE),

with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine
Number of subjects included in analysis	2890
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2265
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.21
Variability estimate	Standard deviation
Dispersion value	0.0604

Secondary: Change From Baseline to 36-38 Weeks of Gestation in Hb Concentration

End point title	Change From Baseline to 36-38 Weeks of Gestation in Hb Concentration

End point description:

Change from Baseline to 36-38 weeks of gestation in Hb concentration was noted. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Baseline, at 36-38 weeks of gestation

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1221[18]	1298[19]		
Units: grams per deciliter (g/dL)				
least squares mean (confidence interval 95%)	0.13 (0.05 to 0.21)	0.27 (0.19 to 0.34)		

Notes:

[18] - N=Number of subjects with available data.

[19] - N=Number of subjects with available data.

Statistical analyses

Statistical analysis title	Change;Baseline-36-38 Weeks;Hb concentration

Statistical analysis description:

Analysis based on an ANCOVA model with model terms for baseline value, treatment group and randomization stratification variable. The 2-sided P-value tests the null hypothesis that the mean difference is 0 (treatment group equality) versus not equal 0.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2519
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0131
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.24
upper limit	-0.03
Variability estimate	Standard error of the mean
Dispersion value	0.05

Secondary: Percentage of Neonates With Congenital Abnormalities at Birth

End point title	Percentage of Neonates With Congenital Abnormalities at Birth

End point description:

Neonates with congenital abnormalities at birth were noted. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1140[20]	1190[21]		
Units: percentage of neonates				
number (confidence interval 95%)	2.19 (1.34 to 3.04)	2.44 (1.56 to 3.31)		

Notes:

[20] - N=Number of total live births.

[21] - N=Number of total live births.

Statistical analyses

Statistical analysis title	Neonates With Congenital Abnormalities at Birth

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6978
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.53
Variability estimate	Standard deviation
Dispersion value	0.2694

Secondary: Percentage of Perinatal or Neonatal Deaths

End point title	Percentage of Perinatal or Neonatal Deaths

End point description:

Percentage of perinatal or neonatal deaths were noted. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Day 28 after delivery

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1140[22]	1190[23]		
Units: percentage of neonates				
number (confidence interval 95%)	2.19 (1.34 to 3.04)	1.85 (1.08 to 2.62)		

Notes:

[22] - N=Number of total live births.

[23] - N=Number of total live births.

Statistical analyses

Statistical analysis title	Percentage of Perinatal or Neonatal Deaths

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6542
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	2.01
Variability estimate	Standard deviation
Dispersion value	0.2908

Secondary: Birth Weight of Live Borne Neonate

End point title	Birth Weight of Live Borne Neonate

End point description:

Birth weight of live borne neonates were calculated in grams. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 was considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1138[24]	1188[25]		
Units: grams				
least squares mean (confidence interval 95%)	3148.3 (3120 to 3176)	3146.2 (3119 to 3174)		

Notes:

[24] - N=Number of live births with available data.

[25] - N=Number of live births with available data.

Statistical analyses

Statistical analysis title	Birth Weight of Live Borne Neonate

Statistical analysis description:

Analysis based on an ANOVA model with model terms for treatment group and randomization stratification variable. The 2-sided P-value tests the null hypothesis that the mean difference is 0 (treatment group equality) versus not equal 0.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2326
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9145
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.5
upper limit	40.8
Variability estimate	Standard error of the mean
Dispersion value	19.71

Secondary: Number of Episodes of Symptomatic Malaria Per Subject From First Intermittent Preventive Treatment of Falciparum Dose to Delivery

End point title	Number of Episodes of Symptomatic Malaria Per Subject From First Intermittent Preventive Treatment of Falciparum Dose to Delivery

End point description:

This outcome measure determined if an episode of malaria started within the time period of first dose to delivery. Clinical episode of malaria was determined if the subject presented with clinical symptoms of malaria (fever >37.5 degree celsius (°C), oral) and diagnosed (either by rapid diagnostic tests or microscopy) with malaria. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1445	1445		
Units: number of episodes				
least squares mean (confidence interval 95%)	0.06 (0.04 to 0.08)	0.13 (0.11 to 0.15)		

Statistical analyses

Statistical analysis title	Symptomatic Malaria

Statistical analysis description:

Analysis based on an ANOVA model with model terms for treatment group and randomization stratification variable. A negative mean difference between treatment groups favors Azithromycin + Chloroquine (reduction in number of symptomatic malaria). The 2-sided P-value tests the null hypothesis that the mean difference is 0 (treatment group equality) versus not equal 0.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2890
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	-0.04
Variability estimate	Standard error of the mean
Dispersion value	0.01

Secondary: Percentage of Subjects Requiring Additional Treatment for Symptomatic Malaria From First Dose to Delivery

End point title	Percentage of Subjects Requiring Additional Treatment for Symptomatic Malaria From First Dose to Delivery

End point description:

This outcome measure evaluated the subjects requiring additional treatments for malaria during the study period following the first dose (diagnosed based on clinical presentation and/or lab test results). ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1445	1445		
Units: percentage of subjects				
number (confidence interval 95%)	5.74 (4.54 to 6.94)	10.52 (8.94 to 12.1)		

Statistical analyses

Statistical analysis title	Additional Treatment for Symptomatic Malaria

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2890
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	0.62
Variability estimate	Standard deviation
Dispersion value	0.1221

Secondary: Percentage of Subjects With Peripheral Parasitemia at 36-38 Weeks of Gestation

End point title	Percentage of Subjects With Peripheral Parasitemia at 36-38 Weeks of Gestation

End point description:

This outcome measure evaluated the percentage of subjects positive for peripheral parasitemia at 36-38 weeks of gestation. A subjects was positive for parasitemia if the number of asexual parasites per microliter (µL) was >0. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

At 36-38 weeks of gestation

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1069[26]	1142[27]		
Units: percentage of subjects				
number (confidence interval 95%)	2.71 (1.74 to 3.68)	4.38 (3.19 to 5.57)		

Notes:

[26] - N = Number of subjects with peripheral blood smear parasite counts at 36-38 weeks of gestation.

[27] - N = Number of subjects with peripheral blood smear parasite counts at 36-38 weeks of gestation.

Statistical analyses

Statistical analysis title	Peripheral Parasitemia at 36-38 Weeks

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2211
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.036
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	0.97
Variability estimate	Standard deviation
Dispersion value	0.2295

Secondary: Percentage of Subjects With Peripheral Parasitemia at Delivery

End point title	Percentage of Subjects With Peripheral Parasitemia at Delivery

End point description:

This outcome measure evaluated the percentage of subjects positive for peripheral parasitemia at delivery. A subject was positive for parasitemia if the number of asexual parasites per µL was >0. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1025[28]	1086[29]		
Units: percentage of subjects				
number (confidence interval 95%)	6.05 (4.59 to 7.51)	7.46 (5.9 to 9.02)		

Notes:

[28] - N = Number of subjects with peripheral blood smear parasite counts at delivery.

[29] - N = Number of subjects with peripheral blood smear parasite counts at delivery.

Statistical analyses

Statistical analysis title	Peripheral Parasitemia at Delivery

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1975
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	1.12
Variability estimate	Standard deviation
Dispersion value	0.163

Secondary: Percentage of Subjects With Cord Blood Parasitemia at Delivery

End point title	Percentage of Subjects With Cord Blood Parasitemia at Delivery

End point description:

This outcome measure evaluated the percentage of subjects positive for cord blood parasitemia at delivery. A subject was positive for parasitemia if the number of asexual parasites per µL was >0. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1015[30]	1072[31]		
Units: percentage of subjects				
number (confidence interval 95%)	0.49 (0.06 to 0.92)	0.75 (0.23 to 1.27)		

Notes:

[30] - N = Number of subjects with cord blood smear parasite counts at delivery.

[31] - N = Number of subjects with cord blood smear parasite counts at delivery.

Statistical analyses

Statistical analysis title	Cord Blood Parasitemia at Delivery

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2087
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4655
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	2.01
Variability estimate	Standard deviation
Dispersion value	0.5675

Secondary: Percentage of Subjects With Sexually Transmitted Infections From First Dose to 36-38 Weeks of Gestation

End point title	Percentage of Subjects With Sexually Transmitted Infections From First Dose to 36-38 Weeks of Gestation

End point description:

Sexual transmitted disease included Treponema pallidum, Neisseria gonorrhoeae, and Chlamydia trachomatis infections. This was diagnosed based on clinical presentation prior to Week 36-38 and/or lab test results between Week 36-38. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Up to 36-38 weeks of gestation

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1445	1445		
Units: percentage of subjects				
number (confidence interval 95%)	12.32 (10.63 to 14.01)	16.47 (14.56 to 18.38)		

Statistical analyses

Statistical analysis title	Sexually Transmitted Infections; 36-38 Weeks

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2890
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0016
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.9
Variability estimate	Standard deviation
Dispersion value	0.0918

Secondary: Percentage of Subjects With Chlamydia Trachomatis Infection at 36-38 Weeks of Gestation

End point title	Percentage of Subjects With Chlamydia Trachomatis Infection at 36-38 Weeks of Gestation

End point description:

Subjects positive for Chlamydia trachomatis infection was diagnosed based on laboratory result at 36-38 weeks of gestation. A vaginal swab was collected and polymerase chain reaction (PCR) assay was used for analysis. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

At 36-38 weeks of gestation

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	746[32]	794[33]		
Units: percentage of subjects				
number (confidence interval 95%)	1.47 (0.61 to 2.33)	0.63 (0.08 to 1.18)		

Notes:

[32] - N=Number of sibjects with lab test results at 36-38 weeks of gestation.

[33] - N=Number of sibjects with lab test results at 36-38 weeks of gestation.

Statistical analyses

Statistical analysis title	Chlamydia Trachomatis Infection at 36-38 Weeks

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	1540
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1113
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	2.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	6.66
Variability estimate	Standard deviation
Dispersion value	0.5338

Secondary: Percentage of Subjects With Neisseria Gonorrhoeae Infection at 36-38 Weeks of Gestation

End point title	Percentage of Subjects With Neisseria Gonorrhoeae Infection at 36-38 Weeks of Gestation

End point description:

Subjects positive for Neisseria gonorrhoeae infection was diagnosed based on laboratory result at 36-38 weeks of gestation. A vaginal swab was collected and PCR assay was used for analysis. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

At 36-38 weeks of gestation

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	746[34]	794[35]		
Units: percentage of subjects				
number (confidence interval 95%)	0.4 (0 to 0.85)	1.64 (0.76 to 2.52)		

Notes:

[34] - N=Number of subjects with laboratory test results at 36-38 weeks of gestation.

[35] - N=Number of subjects with laboratory test results at 36-38 weeks of gestation.

Statistical analyses

Statistical analysis title	Neisseria Gonorrhoeae Infection at 36-38 Weeks

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	1540
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0284
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.07
upper limit	0.86
Variability estimate	Standard deviation
Dispersion value	0.6386

Secondary: Percentage of Subjects With Treponema Pallidum Infection at 36-38 Weeks of Gestation

End point title	Percentage of Subjects With Treponema Pallidum Infection at 36-38 Weeks of Gestation

End point description:

Subjects positive for Treponema pallidum infection was diagnosed based on laboratory result at 36-38 weeks of gestation. Treponema Pallidum particle Agglutination Assay was used. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

At 36-38 weeks of gestation

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	751[36]	797[37]		
Units: percentage of subjects				
number (confidence interval 95%)	0.93 (0.24 to 1.62)	2.01 (1.04 to 2.98)		

Notes:

[36] - N=Number of subjects with laboratory test results at 36-38 weeks of gestation.

[37] - N=Number of subjects with laboratory test results at 36-38 weeks of gestation.

Statistical analyses

Statistical analysis title	Treponema Pallidum Infection at 36-38 Weeks

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Sulfadoxine + Pyrimethamine v Azithromycin + Chloroquine

Number of subjects included in analysis	1548
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0188
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.24
upper limit	0.88
Variability estimate	Standard deviation
Dispersion value	0.3291

Secondary: Percentage of Subjects With Trichomonas Vaginalis Infection at 36-38 Weeks of Gestation

End point title	Percentage of Subjects With Trichomonas Vaginalis Infection at 36-38 Weeks of Gestation

End point description:

Subjects positive for Trichomonas vaginalis infection was diagnosed based on laboratory result at 36-38 weeks of gestation. A vaginal swab was collected for the laboratory test. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

At 36-38 weeks of gestation

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1068[38]	1143[39]		
Units: percentage of subjects				
number (confidence interval 95%)	8.24 (6.59 to 9.89)	10.67 (8.88 to 12.46)		

Notes:

[38] - N=Number of subjects with laboratory test results at 36-38 weeks of gestation.

[39] - N=Number of subjects with laboratory test results at 36-38 weeks of gestation.

Statistical analyses

Statistical analysis title	Trichomonas Vaginalis Infection at 36-38 Weeks

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Sulfadoxine + Pyrimethamine v Azithromycin + Chloroquine

Number of subjects included in analysis	2211
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0527
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	1
Variability estimate	Standard deviation
Dispersion value	0.1336

Secondary: Percentage of Subjects With Bacterial Vaginosis Infection at 36-38 Weeks of Gestation

End point title	Percentage of Subjects With Bacterial Vaginosis Infection at 36-38 Weeks of Gestation

End point description:

Bacterial vaginosis infection was diagnosed based on laboratory result at 36-38 weeks of gestation. A vaginal swab was collected for the Gram staining. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

At 36-38 weeks of gestation

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	746[40]	794[41]		
Units: percentage of subjects				
number (confidence interval 95%)	8.58 (6.57 to 10.59)	11.84 (9.59 to 14.09)		

Notes:

[40] - N=Number of subjects with laboratory test results at 36-38 weeks of gestation.

[41] - N=Number of subjects with laboratory test results at 36-38 weeks of gestation.

Statistical analyses

Statistical analysis title	Bacterial Vaginosis Infection at 36-38 Weeks

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	1540
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0384
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	0.98
Variability estimate	Standard deviation
Dispersion value	0.1536

Secondary: Percentage of Neonates With Ophthalmia Neonatorum at Birth Period

End point title	Percentage of Neonates With Ophthalmia Neonatorum at Birth Period

End point description:

Ophthalmia neonatorum was diagnosed at birth. The laboratory diagnosis was performed among neonates with purulent discharge. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1140[42]	1190[43]		
Units: percentage of neonates				
number (confidence interval 95%)	0.35 (0.01 to 0.69)	0.17 (0 to 0.4)		

Notes:

[42] - N=Total live births.

[43] - N=Total live births.

Statistical analyses

Statistical analysis title	Neonates; Ophthalmia Neonatorum at Birth Period

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3942
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	2.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	11.38
Variability estimate	Standard deviation
Dispersion value	0.8648

Secondary: Percentage of Subjects With Bacterial Infections Including Pneumonia and Other Lower Respiratory Tract Infections From First Dose to Delivery

End point title	Percentage of Subjects With Bacterial Infections Including Pneumonia and Other Lower Respiratory Tract Infections From First Dose to Delivery

End point description:

Subjects positive for bacterial infections including other lower respiratory tract infections (LRTI) were measured anytime from first dose administration to delivery. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

Up to approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1145[44]	1145[45]		
Units: percentage of subjects				
number (confidence interval 95%)	0.48 (0.13 to 0.84)	1.25 (0.67 to 1.82)		

Notes:

[44] - N=Number of subjects with available data.

[45] - N=Number of subjects with available data.

Statistical analyses

Statistical analysis title	Bacterial Infections;Pneumonia;LRTI

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Azithromycin + Chloroquine v Sulfadoxine + Pyrimethamine

Number of subjects included in analysis	2290
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0332
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	0.93
Variability estimate	Standard deviation
Dispersion value	0.4439

Secondary: Percentage of Subjects With Pre-eclampsia From Week 20 to Delivery

End point title	Percentage of Subjects With Pre-eclampsia From Week 20 to Delivery

End point description:

Pre-eclampsia was diagnosed as systolic blood pressure of at least 140 millimeter of mercury (mmHg) and/or diastolic blood pressure of at least 90 mmHg on two separate readings taken at least 4 hours apart and proteinuria at least 300 mg protein in a 24 hour urine collection. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus.

End point type	Secondary

End point timeframe:

From Week 20 to approximately 40 weeks of gestational age

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1140[46]	1143[47]		
Units: percentage of subjects				
number (confidence interval 95%)	0.63 (0.22 to 1.03)	1.04 (0.51 to 1.55)		

Notes:

[46] - N= Number of subjects with available data.

[47] - N= Number of subjects with available data.

Statistical analyses

Statistical analysis title	Pre-Eclampsia; Week 20 to Delivery

Statistical analysis description:

Mantel-Haenszel estimate of the common relative risk is presented, adjusting for randomization strata. A relative risk less than 1 favors Azithromycin + Chloroquine treatment group (reduction in risk for the endpoint). The 2-sided P-value tests the null hypothesis that the relative risk equals 1 (treatment group equality) versus not equal 1. The estimated risk ratio is presented along with its standard error (SE), with the SE on the log(e) scale.

Comparison groups	Sulfadoxine + Pyrimethamine v Azithromycin + Chloroquine

Number of subjects included in analysis	2283
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2321
Method	Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	1.38
Variability estimate	Standard deviation
Dispersion value	0.4195

Secondary: Nasopharyngeal Swabs Positive for Macrolide Resistant Streptococcus Pneumoniae

End point title	Nasopharyngeal Swabs Positive for Macrolide Resistant Streptococcus Pneumoniae

End point description:

This outcome measure evaluated the Streptococcus pneumoniae sensitivity against macrolide antibiotics. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus. Here "N"= Number of subject with nasopharyngeal swabs isolating Streptococcus pneumoniae at specified visit.

End point type	Secondary

End point timeframe:

Visits 6 and 7

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1145	1145		
Units: percentage of subjects				
number (not applicable)				
Visit 6 (N = 8, 17)	0	11.76		
Visit 7 (N = 16, 11)	0	0		

Attachments (see zip file)	Statistical Analysis Attachment/Nasopharyngeal Swabs Positive

Statistical analyses

No statistical analyses for this end point

Secondary: Nasopharyngeal Swabs Positive for Penicillin Resistant Streptococcus

Pneumoniae

End point title	Nasopharyngeal Swabs Positive for Penicillin Resistant Streptococcus Pneumoniae

End point description:

This outcome measure evaluated the Streptococcus pneumoniae sensitivity against penicillin antibiotics. ITT set was used which consisted of subjects who were randomized, received at least one dose of study medication (Day 0 at Visit 1 is considered the first dose of study medication), and who had a single fetus. Here "N"= Number of subject with nasopharyngeal swabs isolating Streptococcus pneumoniae at specified visit.

End point type	Secondary

End point timeframe:

Visits 6 and 7

End point values	Azithromycin + Chloroquine	Sulfadoxine + Pyrimethamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1145	1145		
Units: percentage of subjects				
number (not applicable)				
Visit 6 (N = 8, 17)	0	0		
Visit 7 (N = 16, 11)	0	0		

Attachments (see zip file)	Statistical Analysis Attachment/Nasopharyngeal Swabs Positive

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Visit 7 (6 months post last dose). Includes data up to 35 days after last dose of study drug for mothers (treatment emergent), and includes all data for neonates

Adverse event reporting additional description:

Same event may appear as AE and SAE,what is presented are distinct events. Some events seen only in neonates (neonatal malformation/anomalies, LBW);not expected in mothers and vice versa. Such events designated as '0' in respective 'familial status- neonate/mother'. EU BR specific AE tables generated separately as per EU format using latest coding.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Mother (Azithromycin + Chloroquine)

Reporting group description:

The subjects received 1000 mg Azithromycin (AZ) and 620 mg of Chloroquine (CQ) base (4 combination tablets of AZCQ with individual strength of 250 mg/155 mg), by mouth once daily for 3 days (Days 0, 1, 2) per treatment. There were a total of 3 treatments at 4-8 week intervals. Number of deaths due to adverse events = 3. Number of deaths related to treatment = 0.

Reporting group title	Mother (Sulfadoxine + Pyrimethamine)

Reporting group description:

The subjects received sulfadoxine-pyrimethamine (SP) (Fansidar) treatment course: 1500 mg sulfadoxine and 75 mg pyrimethamine (3 fixed tablets of SP strength at 500 mg/25 mg), single oral dose on Day 0 of each treatment. There were a total of 3 treatments at 4-8 week intervals. Number of deaths due to adverse events = 1. Number of deaths related to treatment = 0.

Reporting group title	Neonate (Azithromycin + Chloroquine)

Reporting group description:

Live births of subjects who received 1000 mg Azithromycin (AZ) and 620 mg of Chloroquine (CQ) base (4 combination tablets of AZCQ with individual strength of 250 mg/155 mg), by mouth once daily for 3 days (Days 0, 1, 2) per treatment. There were a total of 3 treatments at 4-8 week intervals. Number of deaths due to adverse events = 25. Number of deaths related to treatment = 0.

Reporting group title	Neonate (Sulfadoxine + Pyrimethamine)

Reporting group description:

Live births of subjects who received sulfadoxine-pyrimethamine (SP) (Fansidar) treatment course: 1500 mg sulfadoxine and 75 mg pyrimethamine (3 fixed tablets of SP strength at 500 mg/25 mg), single oral dose on Day 0 of each treatment. There were a total of 3 treatments at 4-8 week intervals. Number of deaths due to adverse events = 22. Number of deaths related to treatment = 0.

Serious adverse events	Mother (Azithromycin + Chloroquine)	Mother (Sulfadoxine + Pyrimethamine)	Neonate (Azithromycin + Chloroquine)
Total subjects affected by serious adverse events			
subjects affected / exposed	65 / 1446 (4.50%)	42 / 1445 (2.91%)	101 / 1149 (8.79%)
number of deaths (all causes)	3	1	25
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	3 / 1446 (0.21%)	2 / 1445 (0.14%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous complete			
subjects affected / exposed	2 / 1446 (0.14%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion threatened			
subjects affected / exposed	4 / 1446 (0.28%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eclampsia			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Foetal death			
subjects affected / exposed	3 / 1446 (0.21%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal distress syndrome			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			

subjects affected / exposed	2 / 1446 (0.14%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HELLP syndrome			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage in pregnancy			
subjects affected / exposed	7 / 1446 (0.48%)	1 / 1445 (0.07%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Imminent abortion			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice neonatal			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	3 / 1149 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Low birth weight baby			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	9 / 1149 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Neonatal disorder			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructed labour			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placental disorder			

subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placental infarction			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum haemorrhage			
subjects affected / exposed	2 / 1446 (0.14%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	3 / 1446 (0.21%)	5 / 1445 (0.35%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	17 / 1149 (1.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 7
Premature delivery			
subjects affected / exposed	7 / 1446 (0.48%)	5 / 1445 (0.35%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature labour			
subjects affected / exposed	4 / 1446 (0.28%)	4 / 1445 (0.28%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature rupture of membranes			
subjects affected / exposed	1 / 1446 (0.07%)	2 / 1445 (0.14%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			

subjects affected / exposed	4 / 1446 (0.28%)	3 / 1445 (0.21%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stillbirth			
subjects affected / exposed	5 / 1446 (0.35%)	7 / 1445 (0.48%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Threatened labour			
subjects affected / exposed	3 / 1446 (0.21%)	3 / 1445 (0.21%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical cord around neck			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death neonatal			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 1446 (0.07%)	1 / 1445 (0.07%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal asphyxia			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	6 / 1149 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 4
Neonatal aspiration			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	2 / 1149 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Obstructive airways disorder			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia aspiration			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory distress			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	3 / 1149 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Investigations			
Apgar score low			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
HIV test positive			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Uterine rupture			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Anal atresia			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cerebellar hypoplasia			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Congenital hand malformation			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital malaria			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	3 / 1149 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital umbilical hernia			

subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	2 / 1149 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystic lymphangioma			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysmorphism			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exomphalos			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart disease congenital			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypospadias			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	2 / 1149 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microgenia			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Polydactyly			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	16 / 1149 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Talipes			

subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Tricuspid valve disease			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Tricuspid valve incompetence			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			
Convulsion			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	3 / 1446 (0.21%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	3 / 1149 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic disease of newborn			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 1446 (0.00%)	1 / 1445 (0.07%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	3 / 1446 (0.21%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising colitis			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectourethral fistula			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Umbilical hernia			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	2 / 1149 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis cholestatic			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Jaundice			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 1446 (0.00%)	1 / 1445 (0.07%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal vessel disorder			
subjects affected / exposed	0 / 1446 (0.00%)	1 / 1445 (0.07%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot deformity			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholin's abscess			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			

subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 1446 (0.00%)	1 / 1445 (0.07%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	2 / 1446 (0.14%)	9 / 1445 (0.62%)	2 / 1149 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Meningitis			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Neonatal infection			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	5 / 1149 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	1 / 1446 (0.07%)	1 / 1445 (0.07%)	9 / 1149 (0.78%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 4
Pyelonephritis acute			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	2 / 1149 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis neonatal			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	11 / 1149 (0.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin bacterial infection			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 1446 (0.00%)	2 / 1445 (0.14%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	1 / 1446 (0.07%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral rash			

subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	1 / 1149 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic disorder			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Neonate (Sulfadoxine + Pyrimethamine)		
Total subjects affected by serious adverse events			
subjects affected / exposed	104 / 1196 (8.70%)		
number of deaths (all causes)	22		
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			

subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abortion spontaneous complete			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abortion threatened			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eclampsia			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal death			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal distress syndrome			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gestational hypertension			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HELLP syndrome			

subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhage in pregnancy			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Imminent abortion			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Jaundice neonatal			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Low birth weight baby			
subjects affected / exposed	10 / 1196 (0.84%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 3		
Neonatal disorder			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obstructed labour			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Placental disorder			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Placental infarction			

subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postpartum haemorrhage			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pre-eclampsia			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature baby			
subjects affected / exposed	12 / 1196 (1.00%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 6		
Premature delivery			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature labour			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature rupture of membranes			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Preterm premature rupture of membranes			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stillbirth			

subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Threatened labour			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical cord around neck			
subjects affected / exposed	2 / 1196 (0.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Death neonatal			
subjects affected / exposed	2 / 1196 (0.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Pyrexia			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			

subjects affected / exposed	1 / 1196 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neonatal asphyxia				
subjects affected / exposed	9 / 1196 (0.75%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 5			
Neonatal aspiration				
subjects affected / exposed	5 / 1196 (0.42%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 1			
Neonatal respiratory distress syndrome				
subjects affected / exposed	4 / 1196 (0.33%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Obstructive airways disorder				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	3 / 1196 (0.25%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Respiratory arrest				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	1 / 1196 (0.08%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 1			
Investigations				
Apgar score low				

subjects affected / exposed	1 / 1196 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
HIV test positive			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Uterine rupture			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Anal atresia			
subjects affected / exposed	1 / 1196 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebellar hypoplasia			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital hand malformation			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital malaria			
subjects affected / exposed	2 / 1196 (0.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Congenital umbilical hernia			
subjects affected / exposed	2 / 1196 (0.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Cystic lymphangioma			
subjects affected / exposed	1 / 1196 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Dysmorphism			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Exomphalos			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Heart disease congenital			
subjects affected / exposed	1 / 1196 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Hypospadias			
subjects affected / exposed	1 / 1196 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Microgenia			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polydactyly			
subjects affected / exposed	21 / 1196 (1.76%)		
occurrences causally related to treatment / all	0 / 21		
deaths causally related to treatment / all	0 / 0		
Talipes			
subjects affected / exposed	1 / 1196 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			

Tricuspid valve disease			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tricuspid valve incompetence			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Convulsion			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 1196 (0.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic disease of newborn			
subjects affected / exposed	1 / 1196 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Necrotising colitis				
subjects affected / exposed	1 / 1196 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectourethral fistula				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				
subjects affected / exposed	3 / 1196 (0.25%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Hepatitis cholestatic				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice				

subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal vessel disorder			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Foot deformity			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	1 / 1196 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bartholin's abscess			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia			
subjects affected / exposed	2 / 1196 (0.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Cellulitis				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	2 / 1196 (0.17%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	1 / 1196 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malaria				
subjects affected / exposed	3 / 1196 (0.25%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	1 / 1196 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Neonatal infection				
subjects affected / exposed	4 / 1196 (0.33%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	10 / 1196 (0.84%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 2			
Pyelonephritis acute				

subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	3 / 1196 (0.25%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Sepsis neonatal				
subjects affected / exposed	13 / 1196 (1.09%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 1			
Skin bacterial infection				
subjects affected / exposed	1 / 1196 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Varicella				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral rash				
subjects affected / exposed	0 / 1196 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				

subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	1 / 1196 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malnutrition			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic disorder			
subjects affected / exposed	1 / 1196 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Mother (Azithromycin + Chloroquine)	Mother (Sulfadoxine + Pyrimethamine)	Neonate (Azithromycin + Chloroquine)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1177 / 1446 (81.40%)	888 / 1445 (61.45%)	301 / 1149 (26.20%)
Pregnancy, puerperium and perinatal conditions			
Low birth weight baby			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	29 / 1149 (2.52%)
occurrences (all)	0	0	29
Premature baby			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	28 / 1149 (2.44%)
occurrences (all)	0	0	28
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	239 / 1446 (16.53%)	40 / 1445 (2.77%)	0 / 1149 (0.00%)
occurrences (all)	239	40	0
Fatigue			

subjects affected / exposed	81 / 1446 (5.60%)	22 / 1445 (1.52%)	0 / 1149 (0.00%)
occurrences (all)	81	22	0
Pyrexia			
subjects affected / exposed	10 / 1446 (0.69%)	26 / 1445 (1.80%)	40 / 1149 (3.48%)
occurrences (all)	10	26	40
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	15 / 1446 (1.04%)	10 / 1445 (0.69%)	0 / 1149 (0.00%)
occurrences (all)	15	10	0
Investigations			
White blood cells urine positive			
subjects affected / exposed	149 / 1446 (10.30%)	162 / 1445 (11.21%)	0 / 1149 (0.00%)
occurrences (all)	149	162	0
Injury, poisoning and procedural complications			
Perineal injury			
subjects affected / exposed	19 / 1446 (1.31%)	20 / 1445 (1.38%)	0 / 1149 (0.00%)
occurrences (all)	19	20	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	460 / 1446 (31.81%)	84 / 1445 (5.81%)	0 / 1149 (0.00%)
occurrences (all)	460	84	0
Headache			
subjects affected / exposed	300 / 1446 (20.75%)	219 / 1445 (15.16%)	0 / 1149 (0.00%)
occurrences (all)	300	219	0
Somnolence			
subjects affected / exposed	38 / 1446 (2.63%)	0 / 1445 (0.00%)	0 / 1149 (0.00%)
occurrences (all)	38	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	205 / 1446 (14.18%)	192 / 1445 (13.29%)	21 / 1149 (1.83%)
occurrences (all)	205	192	21
Eye disorders			
Vision blurred			
subjects affected / exposed	145 / 1446 (10.03%)	1 / 1445 (0.07%)	0 / 1149 (0.00%)
occurrences (all)	145	1	0

Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	123 / 1446 (8.51%)	50 / 1445 (3.46%)	0 / 1149 (0.00%)
occurrences (all)	123	50	0
Abdominal pain			
subjects affected / exposed	120 / 1446 (8.30%)	36 / 1445 (2.49%)	0 / 1149 (0.00%)
occurrences (all)	120	36	0
Abdominal pain lower			
subjects affected / exposed	50 / 1446 (3.46%)	45 / 1445 (3.11%)	0 / 1149 (0.00%)
occurrences (all)	50	45	0
Diarrhoea			
subjects affected / exposed	205 / 1446 (14.18%)	14 / 1445 (0.97%)	0 / 1149 (0.00%)
occurrences (all)	205	14	0
Dyspepsia			
subjects affected / exposed	8 / 1446 (0.55%)	15 / 1445 (1.04%)	0 / 1149 (0.00%)
occurrences (all)	8	15	0
Gastritis			
subjects affected / exposed	23 / 1446 (1.59%)	7 / 1445 (0.48%)	0 / 1149 (0.00%)
occurrences (all)	23	7	0
Nausea			
subjects affected / exposed	216 / 1446 (14.94%)	58 / 1445 (4.01%)	0 / 1149 (0.00%)
occurrences (all)	216	58	0
Vomiting			
subjects affected / exposed	650 / 1446 (44.95%)	96 / 1445 (6.64%)	0 / 1149 (0.00%)
occurrences (all)	650	96	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	46 / 1446 (3.18%)	23 / 1445 (1.59%)	0 / 1149 (0.00%)
occurrences (all)	46	23	0
Pruritus generalised			
subjects affected / exposed	22 / 1446 (1.52%)	8 / 1445 (0.55%)	0 / 1149 (0.00%)
occurrences (all)	22	8	0
Musculoskeletal and connective tissue disorders			
Back pain			

subjects affected / exposed	33 / 1446 (2.28%)	29 / 1445 (2.01%)	0 / 1149 (0.00%)
occurrences (all)	33	29	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	15 / 1149 (1.31%)
occurrences (all)	0	0	15
Gastroenteritis			
subjects affected / exposed	44 / 1446 (3.04%)	21 / 1445 (1.45%)	48 / 1149 (4.18%)
occurrences (all)	44	21	48
Infection parasitic			
subjects affected / exposed	14 / 1446 (0.97%)	18 / 1445 (1.25%)	0 / 1149 (0.00%)
occurrences (all)	14	18	0
Malaria			
subjects affected / exposed	49 / 1446 (3.39%)	121 / 1445 (8.37%)	37 / 1149 (3.22%)
occurrences (all)	49	121	37
Pneumonia			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	34 / 1149 (2.96%)
occurrences (all)	0	0	34
Sepsis			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	18 / 1149 (1.57%)
occurrences (all)	0	0	18
Sepsis neonatal			
subjects affected / exposed	0 / 1446 (0.00%)	0 / 1445 (0.00%)	21 / 1149 (1.83%)
occurrences (all)	0	0	21
Trichomoniasis			
subjects affected / exposed	58 / 1446 (4.01%)	55 / 1445 (3.81%)	0 / 1149 (0.00%)
occurrences (all)	58	55	0
Upper respiratory tract infection			
subjects affected / exposed	127 / 1446 (8.78%)	153 / 1445 (10.59%)	125 / 1149 (10.88%)
occurrences (all)	127	153	125
Urinary tract infection			
subjects affected / exposed	105 / 1446 (7.26%)	115 / 1445 (7.96%)	0 / 1149 (0.00%)
occurrences (all)	105	115	0
Vulvovaginal candidiasis			

subjects affected / exposed	75 / 1446 (5.19%)	60 / 1445 (4.15%)	0 / 1149 (0.00%)
occurrences (all)	75	60	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	44 / 1446 (3.04%)	11 / 1445 (0.76%)	0 / 1149 (0.00%)
occurrences (all)	44	11	0

Non-serious adverse events	Neonate (Sulfadoxine + Pyrimethamine)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	326 / 1196 (27.26%)		
Pregnancy, puerperium and perinatal conditions			
Low birth weight baby			
subjects affected / exposed	39 / 1196 (3.26%)		
occurrences (all)	39		
Premature baby			
subjects affected / exposed	28 / 1196 (2.34%)		
occurrences (all)	28		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	28 / 1196 (2.34%)		
occurrences (all)	28		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Investigations			
White blood cells urine positive			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		

Injury, poisoning and procedural complications			
Perineal injury			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	14 / 1196 (1.17%)		
occurrences (all)	14		
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Abdominal pain lower			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Dyspepsia			

subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Pruritus generalised			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	10 / 1196 (0.84%)		
occurrences (all)	10		
Gastroenteritis			
subjects affected / exposed	37 / 1196 (3.09%)		
occurrences (all)	37		
Infection parasitic			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Malaria			
subjects affected / exposed	37 / 1196 (3.09%)		
occurrences (all)	37		
Pneumonia			

subjects affected / exposed	25 / 1196 (2.09%)		
occurrences (all)	25		
Sepsis			
subjects affected / exposed	9 / 1196 (0.75%)		
occurrences (all)	9		
Sepsis neonatal			
subjects affected / exposed	21 / 1196 (1.76%)		
occurrences (all)	21		
Trichomoniasis			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	116 / 1196 (9.70%)		
occurrences (all)	116		
Urinary tract infection			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 1196 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 March 2013	1. A new key secondary endpoint which was comprised of the primary endpoint for sub-optimal pregnancy outcome (as defined) and the addition of congenital malformations and neonatal deaths.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

This program was terminated by Pfizer based on the results of the pre-planned interim analysis for this pivotal study. The interim analysis showed no benefit of the study drug (AZCQ) compared to standard of care (SP).

Notes: