ISRCTN12394097 https://doi.org/10.1186/ISRCTN12394097

Safety and efficacy of artemether-lumefantrine therapy for Intermittent Preventive Treatment in pregnancy in Uganda

Submission date	Recruitment status	[X] Prospectively registered
04/10/2006	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2006	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/10/2011	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A60044 (MAL IRM 06 02)

Study information

Scientific Title

Study objectives
In areas where there is high documented case management resistance to Sulfadoxine-Pyramethamine (SP), artemether-lumefantrine if used for Intermittent Preventive Treatment in pregnancy (IPTp) and given to pregnant women between a gestation of 20 weeks and 28 weeks is more efficacious than SP and can decrease by 85% associated placental malaria infection.

The aims of this trial are:
1. To assess the efficacy of the use of artemether-lumefantrine as IPTp compared with the use of SP for IPTp on the reduction of prevalence of placental parasitaemia at delivery amongst pregnant women
2. To assess the efficacy of the use of artemether-lumefantrine as IPTp in pregnancy compared with the use of SP for IPTp on reduction of Low Birth Weight (LBW), peripheral parasiteamia, anaemia at 34 weeks and at delivery and decrease in clinical episodes of malaria
3. To assess the safety and tolerability of artemether-lumefantrine as IPTp in pregnancy
4. To determine the prevalence of molecular markers of resistance to SP and artemether-lumefantrine amongst pregnant women
5. To assess the health status of mothers and growth development in babies up to one year after delivery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Institutional Review and Ethical Board of St Raphael of St. Francis Hospital, Nsambya P.O. Box 7146 Kampala, Uganda
2. Uganda National Council for Science and Technology .P.O. Box 6884 Kampala, Uganda
3. World Health Organization Headquarters Ethics Review Committee, Geneva

Study design
Open labelled randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Malaria in pregnancy

Interventions
Study Arm A: Artemether-lumefantrine given as four tablets twice daily for three days for each IPTp dose three times during the pregnancy
Study Arm B: Sulphadoxine-pyrimethamine given as three tablets for one day for each IPTp dose three times during the pregnancy.

Each dose for each arm will be repeated after 28 days.

The Principal Investigator for this trial:
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Please note, as of 24/09/2009 this trial was stopped by the sponsor (WHO) as monitoring of the trial was not adequate.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Artemether-lumefantrine

Primary outcome measure
Prevalence and severity of placental parasitaemia at delivery

Secondary outcome measures
1. Prevalence of low birth weight (less than 2500 g) at delivery
2. Prevalence and severity of peripheral parasitaemia during pregnancy until delivery
3. Prevalence of anaemia (haemoglobin less than 10 g/dl) at 34 weeks and at delivery

Overall study start date
12/02/2007

Completion date
30/09/2009

Reason abandoned (if study stopped)

Objectives no longer viable/Lack of sponsorship

Eligibility

Key inclusion criteria
1. Pregnant with a gestational age between 20 to 28 weeks
2. Residing within a radius of 20 miles from the hospital
3. Attending AnteNatal Clinic (ANC) and has not yet received regular programme IPTp with SP
4. Attending ANC and last received anti-malarial treatment greater than one month ago
5. Gives informed consent for study participation
6. Able to come for follow-up

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
1664

Key exclusion criteria
1. Known allergy to SP or artemether-lumefantrine
2. Previously diagnosed with Glucose-6-phosphate dehydrogenase deficiency
3. Presently ill with a medical condition requiring admission to hospital
4. Known patient with cardiac disease or arrhythmia
5. Intrauterine foetal death in the current pregnancy

Date of first enrolment
12/02/2007

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
Switzerland

Uganda

Study participating centre
Implementation Research and Methods (IRM)/Special Programme for Research and Training in Tropical Diseases (TDR)/Centre for Communicable Diseases (CDS)
Geneva-27

Switzerland
CH 1211

Sponsor information

Organisation
UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

Sponsor details
World Health Organization (WHO)
20 Avenue Appia
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Sponsor type
Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
Multilateral Initiative on Malaria (MIM)

Funder Name
United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP)/World Bank/World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration