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Cotrimoxazol to prevent malaria in HIV-infected pregnant women in Sub-Saharan Africa

Submission date
27/08/2012

Recruitment status
No longer recruiting

Registration date
27/09/2012

Overall study status
Completed

Last Edited
13/09/2016

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Malaria is a tropical disease spread by mosquitoes. It affects up to 500 million people each year, killing 1-3 million, mostly pregnant women and children in sub-Saharan Africa. The HIV pandemic disproportionately affects sexually active women in Africa, who as a result are more vulnerable to malaria. Infection with both malaria and HIV during pregnancy leads to anaemia (decreased red blood cells), low birth weight, and increased risk of death. The WHO recommends intermittent preventive treatment (IPT) with the drugs sulphadoxine-pyrimethamine (SP) during pregnancy in areas with a high HIV prevalence. On the other hand, UNAIDS/UNICEF recommend daily treatment with the drugs trimethoprim-sulfamethoxazole (cotrimoxazole: CMX) for all HIV-positive pregnant women. Unfortunately, taking CMX and IPT with SP can cause dangerous side effects for pregnant women and infants, the risk of side-effects being higher in HIV-positive patients. CMX has been proven to protect children and HIV-positive adults against malaria, and CMX alone may be effective at preventing malaria during pregnancy. The aim of this study is to compare the effects of CMX with standard IPT on malaria risk in HIV-pregnant women in rural sub-Saharan Africa.

Who can participate?
HIV-positive pregnant women aged 15 to 45

What does the study involve?
Women are randomly allocated to be treated with either daily CMX or IPT with SP one dose per month until delivery. Women are followed up monthly and are asked to deliver in the study center. At delivery a sample of the placenta is collected. Babies are followed up until the age of 3 months. The number of malaria cases, pregnancy outcome and birth weights are measured in both groups.

What are the possible benefits and risks of participating?
All treatments and tests are free of charge. All pregnant women receive a mosquito net treated with insecticide. Treatment to prevent mother-to-child transmission of HIV follows the national and WHO guidelines. The main side effects of the study drugs are anaemia and skin allergy.

Where is the study run from?
Nineteen health centers participated in the study: CMS Noepe, Hôpital Assahoun, Hôpital Agou-Gare, Hôpital Agou Bethesda, CMS Kpogandji, CMS Kpadapé, CHP Kpalimé, Polyclinique Kpalimé, CMS Adéta, CMS Goudévé, Hôpital Danyi, Hôpital Notsè, Hôpital Anié, CMS Glei, CMS Agbonou, Polyclinique Atakpamé, Hôpital Atakpamé, CMS Akparè, CMS Témédja.

When is the study starting and how long is it expected to run for?
January 2009 to August 2012

Who is funding the study?
AlterSanté (France)

Who is the main contact?
Dr Elise Klement
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Effectiveness of Trimethoprim-Sulfamethoxazole to prevent malaria in HIV-infected pregnant women in P. falciparum-endemic Sub-Saharan Africa: a randomized controlled trial

Study objectives
Cotrimoxazol is non inferior to standard intermittent preventive treatment (IPT) on malaria risk in Human immunodeficiency virus (HIV) pregnant women in rural sub-Saharan Africa.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Togolese National Ethic Committee, January 2009

Study design
Multicenter open-label non-inferiority randomized study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Malaria HIV vertical transmission

Interventions
Women who volunteered were randomized to receive either daily 80/400mg trimethoprim-sulfamethoxazole (CMX) or intermittent preventive treatment (IPT) with 1000/50mg sulfadoxine-pyrimethamine (SP) as follows: first dose at inclusion day, then 1 dose per month until delivery. Women were followed monthly clinically and biologically (Hb and blood smear) free of charge, and were asked to deliver in the study center. At delivery a placenta sample was collected. Babies were followed until the age of 3 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Trimethoprim-sulfamethoxazole, sulfadoxine-pyrimethamine

Primary outcome measure

Incidence of malaria during pregnancy, calculated as the number of malaria events per person year.

Secondary outcome measures
1. Blood parasitaemia in women and new-born
2. Treatment tolerance
3. Pregnancy outcome
4. Birth weight
5. Placental malarial infection

Overall study start date
01/01/2009

Completion date
31/08/2012

Eligibility

Key inclusion criteria
1. HIV1
2. Women <28 weeks of pregnancy
3. CD4 >200/mm3
4. Hb >7 g/L

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
300

Key exclusion criteria
1. Age<15
2. HIV2 or HIV1+2
3. Allergy or ongoing sulfamides treatment

Date of first enrolment
01/01/2009

Date of final enrolment
31/08/2012

Locations

Countries of recruitment

France

Togo

Study participating centre
Centre Médical de Bligny
Briis-sous-forges
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91640

Sponsor information

Organisation
AlterSanté (France)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.altersante.org

ROR
https://ror.org/03sfwdd85

Funder(s)

Funder type
Research organisation

Funder Name
AlterSanté (France)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2014		Yes	No