ISRCTN48295733 https://doi.org/10.1186/ISRCTN48295733

Safety of rectal artesunate in pregnancy - an assessment of pregnancy outcomes in a randomised controlled trial in Bangladesh

Submission date 05/04/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/06/2005	**Overall study status** Completed	
Last Edited 22/10/2007	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A30248

Study information

Scientific Title

Study objectives
Evaluation of the risks associated with the use of artesunate in pregnancy in comparison to placebo.

This study follows up pregnant women exposed to treatment within a larger trial: ISRCTN83979018 - Evaluate impact of rectal artesunate on resolution of severe malaria and mortality (Bangladesh).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained on 10.11.03 from the Secretariat Committee on Research Involving Human Subjects and (continuing review) on 19.10 2005 from the World Health Organization (WHO) Ethics Committee.

Study design
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
Artesunate use in pregnancy

Interventions
A single dose of either 400 mg artesunate suppository or an identical placebo suppository is given.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Artesunate

Primary outcome measure
As this study is a sub-study within a larger trial that has mortality as the main outcome, this should be considered as the same outcome for this trial.

Secondary outcome measures
1. Proportion of anomalies in live-born, proportion of stillborn and late foetal deaths (artesunate versus placebo)
2. Determination of effect on foetal viability in second and third trimester and inadvertent exposures in first trimester (artesunate and placebo)
3. Determination of neonatal and maternal mortality (artesunate versus placebo)
4. Assessment of developmental delays (artesunate versus placebo)
5. Determination of proportion of children with low birth weight (artesunate versus placebo) in the subgroup of patients assessed prospectively

Overall study start date
10/11/2003

Completion date
01/01/2006

Eligibility

Key inclusion criteria
1. Pregnant women
2. Consent of patient or parent/guardian
3. Participation in survival benefit of early treatment with rectal artesunate

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
684

Key exclusion criteria
1. Males
2. Non pregnant female enrolled into study ISRCTN83979018
3. Absence of informed consent from patient or parent/guardian

Date of first enrolment
10/11/2003

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
Bangladesh

Switzerland

Study participating centre
20, Avenue Appia
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
20, Avenue Appia
Geneva -27
Switzerland
CH 1211

Sponsor type
Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

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)

Funder Name
European Commission (Belgium)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
WHO Global Malaria Programme

Funder Name
US Agency for International Development (USAID) (USA)

Funder Name
Irish Aid (Ireland)

Funder Name
Karolinska Institutet (Sweden)

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Sall Family Foundation (USA)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
University of Oxford Clinical Trial Service Unit (UK)

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