

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	<input type="checkbox"/> Prospectively registered
Registration date 07/06/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/10/2007	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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, 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary