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Evaluate impact of rectal artesunate on resolution of severe malaria and mortality (Bangladesh)

Submission date	Recruitment status	[_] Prospectively registered
01/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/02/2009	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
N/A

Study information

Scientific Title

Study objectives
The objective has been to establish whether, in patients with acute malaria who cannot take medication by mouth, rectal artesunate plus referral differs from rectal placebo plus referral in terms of death or permanent disability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received on the 8th July 1998.

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
Malaria

Interventions
The sample size determination in the protocol specified that a total of 10,000 non per os patients would need to be randomised in order to detect a reduction of mortality from 5% to 3%.

Individual patients will be randomised to receive either AS suppository (intervention group) or placebo (comparator group). Patients in both groups will then be referred immediately to the nearest hospital/health centre where all supportive treatment will be provided.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
1. Number of relevant deaths in the intervention and control arm assessed 7 - 30 days after enrolment (relevant defined as malaria positive patients in whom the death was probably /definitely preventable by the intervention)
2. Number of individuals with serious neurological disability in the intervention and control arms assessed at 7 - 30 days following enrolment in the study. Neurological disability defined as the development of new problems with feeding, walking, talking, sitting, sight, hearing, playing, balance and behaviour

Secondary outcome measures
1. Number of deaths in the intervention and control arm assessed 7 - 30 days following enrolment in the study
2. Number of cases of neurological disability in the intervention and control arms assessed at 7 - 30 days following enrolment in the study
3. Number of cases of neurological disability in malaria smear positive patients in the intervention and control arms assessed at 7 - 30 days following enrolment in the study
4. Number of cases of neurological disability in children in the intervention and control arms assessed at 7 - 30 days following enrolment in the study
5. Number of cases of neurological disability in pregnant women in the intervention and control arms assessed at 7 - 30 days following enrolment in the study
6. Number of deaths and neurological sequelae in the intervention and control arm in malaria smear positive patients who survived at least 8 hours but died before 7 days after enrolment in the study

Overall study start date
08/07/1998

Completion date
08/07/2000

Eligibility

Key inclusion criteria
1. Children above crawling age and adults of any age group
2. Clinical diagnosis of probable P. falciparum malaria (fever, or history of fever without any other obvious cause of fever). Clinical features must include fever or history of fever and at least one of the following:
2.1. Unable to take food, drink or suck
2.2. Prostration: inability to sit, stand or walk unaided
2.3. Any abnormal level of consciousness i.e. from abnormal behavior, obtunded (limited response to painful stimulus), to coma (unconsciousness with absent verbal response and non-specific or absent motor response)
2.4. Fits or history of fits (defined as more than one fit in the previous 24 hours)
3. Consent by patient or parent/guardian if patient is less than 18
4. Community informed consent - at the start of the study in that area, community consent to the project would have been obtained

Participant type(s)

Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
In this trial, it is not the number of patients recruited but the number of deaths that determine the statistical power of such a trial.

Key exclusion criteria
1. Afebrile (history/examination)
2. Unwillingness to sign (or parental signature) informed consent for study participation
3. Ability to take oral medication
4. Diarrhoea (at least two loose bowel movements in the previous two hours)
N.B. Pregnant or breast-feeding women will not be excluded from the study. Status of pregnancy in female will be noted in the Case Record Form (CRF).

Date of first enrolment
08/07/1998

Date of final enrolment
08/07/2000

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
Sources of funding:

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/02/2009		Yes	No