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A research study to compare 2 antibacterial drugs, gatifloxacin with ciprofloxacin, for the treatment of dysentery in children

Submission date 15/01/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/01/2008	**Overall study status** Completed	
Last Edited 13/03/2013	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Vinh Ha

Contact details
Oxford University Clinical Research Unit
Hospital for Tropical Diseases
Ho Chi Minh City
Viet Nam
5
+84 8 9237954
vinhh@oucru.org

Additional identifiers

Protocol serial number
061330

Study information

Scientific Title

A randomised controlled trial of gatifloxacin versus ciprofloxacin for the treatment of bacillary dysentery in children

Acronym
EG

Study objectives
In 2004, The World Health Organization (WHO) organised a meeting of experts around the world and recommended that ciprofloxacin or other fluoroquinolones should be used to treat shigellosis in children as well as adults. However after being used for some years to treat shigellosis, the clinical response to ciprofloxacin treatment has decreased, strains of Shigella dysenteriae type 1 resistant to ciprofloxacin were also detected. This is why searching for alternative regimens is obviously needed. This study will compare the currently recommended WHO regimen with a newer, affordable and potentially more active fluoroquinolone, i.e., gatifloxacin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from Oxford Tropical Research Ethics Committee on the 20th June 2006 (ref: OXTREC 010-06).

Primary study design
Interventional

Study design
Open-label randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Shigella dysentery

Interventions
Patients are randomised to:
1. Ciprofloxacin 15 mg/kg body weight taken orally every 12 hours for a total of 6 doses in 3 days, or
2. Gatifloxacin 10 mg/kg body weight taken orally every 24 hours for a total of 3 doses in 3 days

Follow-up will occur for 7 - 10 days after discharge from the hospital.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Ciprofloxacin, gatifloxacin

Primary outcome(s)
Failure of treatment:
1. Persistent fever at Day 5
2. Failure to clear completely the admission symptoms at Day 5
3. Stool culture positive at Day 3 of treatment
4. Need for rescue treatment with ceftriaxone
5. The development on treatment of any complication

Key secondary outcome(s)
1. Fever clearance time: from the start of treatment until axillary temperature falls to 37.5°C and remains at or below this value for greater than 48 hours
2. Bloody diarrhoea clearance time: the time to the last stool containing visible blood passed
3. Diarrhoea clearance time: the time to the first formed stool
4. Bacterial clearance time: time to the last positive stools culture for Shigella

Completion date
30/03/2009

Eligibility

Key inclusion criteria
1. Patients aged 0 - 14, either sex
2. Symptomatic uncomplicated dysentery
3. Gives consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 Years

Upper age limit
14 Years

Sex
All

Key exclusion criteria
No consent given.

Date of first enrolment
01/06/2006

Date of final enrolment
30/03/2009

Locations

Countries of recruitment
Viet Nam

Study participating centre
Oxford University Clinical Research Unit
Ho Chi Minh City
Viet Nam
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Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 061330)

Results and Publications

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	15/12/2009		Yes	No
Results article	results	01/08/2011		Yes	No