ISRCTN34440093 https://doi.org/10.1186/ISRCTN34440093

Effect of Chinese herbal medicine Goreisan (Wulingsan) on vomiting with acute watery diarrhoea in children

Submission date	Recruitment status	[_] Prospectively registered
05/04/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/04/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/04/2009	Infections and Infestations	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Effect of Chinese herbal medicine Goreisan (Wulingsan) on vomiting with acute watery diarrhoea in children: a randomised, double-blind, placebo-controlled clinical trial

Study objectives
Goreisan is effective in reducing the frequency of acute diarrhoea and associated vomiting in children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Review Board of Institute of Child and Mother Health (ERB-ICMH) approved on the 1st April 2008

Study design
Prospective randomised, double-blind, placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Acute gastroenteritis with vomiting and diarrhoea

Interventions
Subjects will be stratified by sex and randomised to Goreisan (Wulingsan) powder or placebo orally in a dose of 0.25 g/kg/day (maximum of 6.0 g/day) twice a day for 3 days.

Contact details for joint Principal Investigator:
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Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Goreisan (Wulingsan)

Primary outcome measure
1. Time to stopping of vomiting and diarrhoea after giving medicine or placebo during 72 hours of observation
2. Frequency of vomiting and diarrhoea after giving medicine or placebo during 72 hours of observation

Secondary outcome measures
1. Recovery from dehydration measured by WHO classification of dehydration in children with diarrhoea
2. Amount of oral rehydration sachets (ORS) and intravenous fluid used after giving medicine or placebo during 72 hours of observation

Overall study start date
14/05/2008

Completion date
14/05/2009

Eligibility

Key inclusion criteria
1. Aged six months up to five completed years, either sex
2. Within 3 days onset of vomiting and watery diarrhoea before enrolment
3. Cases of diarrhoea fulfilling World Health Organization (WHO) criteria (loose motion 3 times and over within 24 hours)
4. Patients with diarrhoea who are still vomiting or have at least one episode of spontaneous vomiting within 3 hours before enrolment

Participant type(s)
Patient

Age group

Child

Lower age limit
6 Months

Upper age limit
5 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Severe dehydration (WHO 2003) needing immediate intravenous fluid
2. Bloody diarrhoea
3. Anti-emetics used during this illness
4. Patients with diarrhoea and severe malnutrition
5. Any signs suggesting bacterial infections that need immediate antibiotic therapy
6. Any signs suggesting meningitis
7. Any signs suggesting ileus and/or intussusception
8. Any signs of serious systemic illness
9. Underlying congenital gastrointestinal disease
10. Other severe underlying diseases (i.e., cancer, acquired immune deficiency syndrome [AIDS], other immuno-compromised patients)
11. Past history of hospitalisation due to severe anaphylaxis to any kinds of foods or liquids

Date of first enrolment
14/05/2008

Date of final enrolment
14/05/2009

Locations

Countries of recruitment
Bangladesh

Study participating centre
Assistant Professor of Paediatrics
Dhaka
Bangladesh
1362

Sponsor information

Organisation
The Institute of Child and Mother Health (ICMH) (Bangladesh)

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Sponsor type
Government

Website
http://www.icmh.org.bd/

ROR
https://ror.org/05dm6kv37

Funder(s)

Funder type
Industry

Funder Name
Kotaro Pharmaceutical Co., Ltd (Japan)

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