

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

Submission date 05/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/04/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/04/2009	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

Contact name

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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)

Sponsor details

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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