ISRCTN53730137 https://doi.org/10.1186/ISRCTN53730137

Doubleblind randomised multicenter trial to investigate the influence of dimenhydrinate suppositories versus placebo on oral rehydration in infants and children with infectious enteritis and vomiting

Submission date 30/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/10/2005	**Overall study status** Completed	
Last Edited 26/10/2009	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Holm Uhlig

Contact details
Universitätsklinik und Poliklinik für Kinder und Jugendliche
Universität Leipzig
Oststraße 21-25
Leipzig
Germany
04317
+49 (0)341 97 26 111
holm.uhlig@medizin.uni-leipzig.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VomED final

Study information

Scientific Title

Acronym
VomED

Study objectives
Is it possible to reduce dehydration due to vomiting in the initial phase of enteritis with vomiting with Dimenhydrinate suppositories (weight adapted dosage) in comparison to placebo in children? Better rehydration is measured by weight gain in between visit 1 and 2 (visit 2 is 18-24 hours after visit 1).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Infectious enteritis with vomiting

Interventions
Treatment with Dimenhydrinate or Placebo in the following dosage:
7-15 kg body weight: 1-2 Supp at 40 mg/24 hours

15-25 kg body weight: 2-3 Supp at 40 mg/24 hours
>25 kg body weight: 2-4 Supp at 40 mg/24 hours
Treatment for the individual patient: 18-24 hours (from visit 1 to visit 2).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dimenhydrinate suppositories

Primary outcome measure
Relative weight gain from visit 1 to visit 2 (measured as quartile of the weight at visit 1 in stratified rank). Worst rank will be hospitalisation.

Secondary outcome measures
1. Can the number of vomiting episodes between visit 1 and 2 be reduced by dimenhydrinate versus placebo?
2. Is there a reduction in the number of necessary hospitalisations due to infectious enteritis and vomiting in the study population?
3. Is the condition of the child estimated by their caregivers (measured in a visual scale) improved?
4. Furthermore adverse events and adverse drug reactions will be documented

Overall study start date
01/10/2005

Completion date
30/09/2006

Eligibility

Key inclusion criteria
1. Acute vomiting started 8-24 hours prior to the inclusion due to suggested infectious enteritis with at least 2 episodes of vomiting in the last 12 hours
2. Age: 6 months-5 years
3. Weight over 7,000 g
4. Outpatients
5. Informed consent of at least one caregiver

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
5 Years

Sex
Both

Target number of participants
270

Key exclusion criteria
1. Contraindications against the study drug
2. Receipt of the following medications:
2.1. Treatment with medicinal products with suspected interactions with dimenhydrinate
2.2. Treatment with antiemetics or secretion inhibitors
3. Severe disease with one of the following criteria:
3.1. Bloody stool with this disease
3.2. Suggested requirement of intravenous (IV) rehydration
3.3. Confirmed weight loss of more than 7.5% body weight
3.4. Metabolic acidosis (i.e. pH <7.25) and/or electrolyte disturbances (measured by blood test in the emergency clinic originated in the responsibility of the investigator)
4. Suspected lack of cooperation and compliance by the patient or the caregiver(s) or linguistic problems of the parents
5. Participation in other medical trials

Date of first enrolment
01/10/2005

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsklinik und Poliklinik für Kinder und Jugendliche
Leipzig
Germany
04317

Sponsor information

Organisation
University of Leipzig (Germany)

Sponsor details
Ritterstraße 26
Leipzig
Germany
04109

Sponsor type
University/education

ROR
https://ror.org/03s7gtk40

Funder(s)

Funder type
Industry

Funder Name
Hexal - Initiative Kinderarzneimittel (Germany)

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	01/10/2009		Yes	No