

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

Registration date

17/10/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

26/10/2009

Condition category

Infections and Infestations

☐ Individual participant data

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