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Comparison of oral and nasogastric (n/g) rehydration in childhood gastroenteritis

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/12/2014	Digestive System	[ ] 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

Protocol serial number
N0515122182

Study information

Scientific Title
Comparison of oral and nasogastric (n/g) rehydration in childhood gastroenteritis

Study objectives

Hypothesis: The World Health Organisation has published guidelines for use of oral rehydration solution (ORS) in childhood gastroenteritis. The solution can be administered by mouth or via nasogastric (n/g) tube. We hypothesise that oral administration, which is successful in the developing world, will not be effective in the UK. The comparison of the two methods has not been tested in a developed world setting.
Value: Determine the most effective and best tolerated method of rehydration which may reduce hospital admissions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised open controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Digestive System: Gastroenteritis

Interventions
Following an initial 30 min assessment all children who had not successfully taken and tolerated 10 ml/kg oral rehydration solution (ORS) would be approached for trial entry. Parents will be consented by research nurse/PACU registrar. Children would have a baseline set of observations, and clinical assessment of dehydration (according to American Academy of Paediatrics protocol). Standard history taking and examination will be carried out.

Randomisation to oral or n/g group done by pre-prepared packs with sealed, opaque envelopes.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The main outcome measure is percentage weight gain at 4 h from the onset of rehydration

Key secondary outcome(s)
1. Failure of rehydration, defined as follows:
1.1 n/g group: failure to pass n/g after three attempts or vomiting of n/g tube on more than one occasion OR
1.2 Oral group: patient failed to take 80% of expected volume at 2 h or >three vomits from hour
2. Parental satisfaction questionnaires

Completion date
31/03/2007

Eligibility

Key inclusion criteria
Patients aged 3 months to 5 years.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Months

Upper age limit
5 Years

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/12/2002

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North West London Hospitals NHS Trust
Harrow
United Kingdom
HA1 3UJ

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North West London Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration