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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Kiran Nistala

Contact details
Paediatric Ambulatory Care Unit
North West London Hospitals NHS Trust
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised open controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/12/2002

Completion date
31/03/2007

Eligibility

Key inclusion criteria
Patients aged 3 months to 5 years.

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Months

Upper age limit
5 Years

Sex
Not Specified

Target number of participants
88 patients in total, 44 in each group

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North West London Hospitals NHS Trust (UK)

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