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

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

#### 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