

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

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<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/12/2014	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**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