

# Manipulation and Administration of Generic and Innovative Child patient medicines - CLINical STUDy: the acceptability of and preference among four oral dosage forms in infants and preschool children in the Netherlands

<b>Submission date</b> 23/06/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/09/2014	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

It can be difficult to give medicines to young children. Children may not want to take them or spit them out. However, it is very important that children swallow the full dose of a medicine. There is some evidence that the problems giving oral liquid medicines such as suspensions and syrups to young children are more profound than the problems giving oral solid flexible preparations such as powders and minitables. Nevertheless a lot of medicines for young children are only commercially available in their liquid form. We want to study whether this approach is correct or in need of change.

### Who can participate?

Parents of children aged 1 to 4 years.

### What does the study involve?

Parents will be asked to administer four oral dosage forms to their child. Each dosage form should be given twice on one day. Parents will be asked to fill in a participant diary. The first domain should be filled in prior to the study. It includes questions about child and family characteristics. The second domain includes questions for each of the eight administrations as to whether the dosage form has been given, the method of administration, the child's acceptance and the result of the intake. The third domain should be filled in at the end of the study. Parents will be asked to indicate child and parent preference plus additional comments.

### What are the possible benefits and risks of participating?

The risks to the participants are considered negligible. All four dosage forms are commonly used in the Netherlands in children. The parents may refrain from administration whenever they consider this necessary, such as when they are afraid to give the mini-tablet to their child because they think the child cannot swallow it. Parents should stop offering the dosage form

when the child does not want to take it. The dosage forms do not include an active substance i.e. they are placebo (dummy) medicine and this is known to the parents. Parents may explain the study purposes to their child when they consider this necessary (e.g., when the child does not understand why he has to take a medicine when he is not ill). Participating children and their parents may benefit from the study outcomes as soon as the results have been implemented and they (or their children) are in need of a real medicine. The anticipated benefits to children and their parents as a group are the availability of dosage forms that are better tailored to their needs

Where is the study run from?

The dosage forms should be administered by the parents as part of normal family routines. Thus the medicines will mostly be given at home; however, administration at other locations (e.g., when visiting grandparents etc) is also accepted.

When is the study starting and how long is it expected to run for?

The patients will be recruited in 2011 and the dosage forms should be used within their shelf-life.

Who is funding the study?

The study will be funded by two separate agencies of the Ministry of Health, Welfare and Sports in the Netherlands, namely the RIVM and the MEB. The study will be conducted in cooperation with Utrecht University and the STMR.

Who is the main contact?

Diana van Riet-Nales

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Diana van Riet-Nales

### Contact details

Graadt van Roggenweg 500

Utrecht

Netherlands

3503 RG

## Additional identifiers

### Protocol serial number

MAGIC CLINSTUD

## Study information

### Scientific Title

The acceptability of and preference among four oral dosage forms in infants and preschool children in the Netherlands: a randomised cross-over trial

## **Acronym**

MAGIC CLINSTUD

## **Study objectives**

The objective of this study is threefold:

1. To investigate the child and parent acceptance of four oral dosage forms in outpatient infants and preschool children (age 1-4 years) in the Netherlands. The dosage forms include a placebo 4-mm tablet, powder, syrup and suspension, all aimed at a neutral taste.
2. To investigate the child's and parents' preference of these dosage forms at the end of the study.
3. To investigate the impact of the child and family characteristics on the outcomes for the child and parent acceptance and preference.

The data that will be collected to enable the aforementioned three aims to be answered (e.g., how parents are administering a specific dosage form to their child when given the instruction twice daily only) may also be evaluated on their own.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethical approval was waived by the Central Committee on Research involving human subjects (CCMO) on the basis of the Medical Research Involving Human Subjects Act (WMO) in the Netherlands. Hence, approval was obtained from the Institutional Review Board of the Utrecht Institute for Pharmaceutical Sciences (UIPS).

The investigator has sent an inquiry to the CCMO as to whether this trial falls under the range of the WMO and hence, whether it would be subject to medical approval.

## **Study design**

Randomised cross-over clinical trial for the type of the dosage form

## **Primary study design**

Interventional

## **Study type(s)**

Other

## **Health condition(s) or problem(s) studied**

Acceptability/preference of oral dosage forms

## **Interventions**

The intervention will consist of the request to parents to administer four oral dosage forms to their child during normal family routines. Each dosage form should be given twice on one day in the same way the parents should administer a prescribed medicine, but without any physical or psychological compulsion.

Details of Joint Sponsor:

Medicines Evaluation Board in the Netherlands

c/o Christine Gispen

Graadt van Roggenweg 500

P.O. Box 8275, 3503 RG  
Utrecht  
The Netherlands  
Email: cc.gispen@cbg-meb.nl  
Tel: + 31 (0) 88 224 8081

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

1. Child and parent acceptance
2. Child and parent preference

**Key secondary outcome(s)**

No secondary outcome measures

**Completion date**

31/12/2011

**Eligibility****Key inclusion criteria**

Children will be eligible for inclusion in this study if aged 1-4 years and if their parents have mastery of the Dutch language

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

1 years

**Upper age limit**

4 years

**Sex**

All

**Key exclusion criteria**

1. Mentally disabled
2. Having a condition that might have an impact on medication intake or requiring oral medication

3. Hypersensitivity to lactose, having cow's milk allergy or having an allergy of unknown origin
4. A member of staff of the preventive healthcare clinic considered that study participation was inappropriate in view of the family situation

**Date of first enrolment**

01/01/2011

**Date of final enrolment**

31/12/2011

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

Graadt van Roggenweg 500

Utrecht

Netherlands

3503 RG

## Sponsor information

**Organisation**

Utrecht University (Netherlands)

**ROR**

<https://ror.org/04pp8hn57>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute of Public Health and the Environment (RIVM) (Netherlands)

**Funder Name**

Medicines Evaluation Board (Netherlands)

**Alternative Name(s)**

Medicines Evaluation Board, CBG

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Netherlands

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/09/2013		Yes	No