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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

Submission date
23/06/2012

Recruitment status
No longer recruiting

Registration date
24/07/2012

Overall study status
Completed

Last Edited
29/09/2014

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 minitablets. 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 childs 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2011

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

Age group
Child

Lower age limit
1 Years

Upper age limit
4 Years

Sex
Both

Target number of participants
150

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)

Sponsor details
c/o Prof. Dr. A.C.G. Egberts
Faculty of Science
Utrecht Institute for Pharmaceutical Sciences
Division Pharmacoepidemiology & Clinical Pharmacology
PO Box 80 082
Utrecht
Netherlands
3508 TB

Sponsor type
University/education

Website
http://www.uu.nl/Nl/Pages/default.aspx

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Government

Funder Name
National Institute of Pubilc 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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2013		Yes	No