Propiverine hydrochloride in children suffering from overactive bladder and urinary incontinence. A randomised, double-blind, placebo-controlled, parallel grouped multicentre clinical trial

Published: 09-05-2006
Last updated: 14-05-2024

This study is designed to demonstrate superiority of efficacy of Propiverine hydrochloride compared to placebo in children suffering from overactive bladder with urinary incontinence.The primary objective is to compare efficacy of Propiverine...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON30181

Source
ToetsingOnline

Brief title
Propiverine-HCL in children suffering from OAB and urinary incontinence.

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
detrusorinstability, Overactive bladder, urgency

Research involving
Human

Sponsors and support

Primary sponsor: APOGEPHA Arzneimittel GmbH
Source(s) of monetary or material Support: APOGEPHA

Intervention

Keyword: Bladder overactivity, incontinence, propiverine hydrochloride

Outcome measures

Primary outcome

Primary efficacy criteria:

Micturition frequency/24 hours determined per diary documented by parents and

child before and at the end of treatment.

Secondary outcome

Secondary efficacy criteria:

- Occurrence of incontinence episodes/ 7 days determined by questioning

- Number of incontinence episodes / 3 days determined by bladder diary

(parents-child-diary)

- Average voided volume/micturition determined per diary documented by parents

and child before and at the end of treatment

- Course of maximum voiding capacity determined per weekly micturition protocol

documented by child

Evaluation of efficacy by patient, parents and investigator

Study description

Background summary

For more than 20 years urinary incontinence as well as urgency and frequency

has been treated with Propiverine hydrochloride. Since 1985 Apogepha offers for the special patient population of children Mictonetten, a particular dosage form with 5 mg Propiverine hydrochloride.
This enables the prescribing consultant an individual and appropriate dose for children.
A clinical trial in conformity with ICH-GCP showing the same high efficacy and safety as experiences in years of practice have shown, is missing until today. Therefore the present study was designed and will be performed.

Study objective

This study is designed to demonstrate superiority of efficacy of Propiverine hydrochloride compared to placebo in children suffering from overactive bladder with urinary incontinence.

The primary objective is to compare efficacy of Propiverine hydrochloride to placebo in children suffering from overactive bladder with urinary incontinence in terms of micturition frequency per day.

The secondary objective is to compare efficacy and safety of Propiverine hydrochloride to placebo in children suffering from overactive bladder with urinary incontinence.

Study design

A double-blind, randomised, placebo controlled, parallel grouped, multicentre clinical trial
with 21 days run-in period, 8 weeks of treatment,

Intervention

The test drug are Mictonetten® , a coated tablet containing 5 mg Propiverine hydrochloride
Assignment to treatment group depends on body weight.
a) 17.0 - 27.9 kg body weight
10 mg (b.i.d.) Propiverine hydrochloride (2 x 5 mg b.i.d. Mictonetten®)
p.o. or corresponding placebo
b) 28.0 - 45.0 kg body weight
15 mg (b.i.d.) Propiverine hydrochloride (3 x 5 mg b.i.d. Mictonetten®)
p.o. or corresponding placebo ratio of verum to placebo 1 : 1

Study burden and risks

The burden for the patient is minimal and equals the standard procedure and treatment in patients with an overactive baldder. (except for the ecg)
Children, together with the parents, have to visit the hospital four times.

A burden list is mentioned in the protocol on page 5 and the patient information sheet.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Male or female, caucasian children: 5 to 10.
Signed ICD
Body weight of 17-45 kg
Micturation frequency >= 8/day at least in 1 of 3 bladder diary days.
Incontinence episodes (at least 1 within 7 days)

Exclusion criteria

Bladder capacity [ml] >= ((age +1) x 30) [ml]
Post void residual > 10 ml
Treatment of overactive bladder symptoms in the last 28 days
Urinary tract infection at the time of study inclusion and other acute and parasitic infections of the genitourinary tract
Enuresis nocturna
Dysfunctional voiding and detrusor-sphincter-dyssynergy
Constipation
Forbidden concomitant medication (see chapter 9.4.7 of the protocol)
Clinical relevant disease of the kidney, liver, gastro-intestinal tract, cardiovascular system metabolism disorder (e.g. juvenile diabetes mellitus, diabetes insipidus

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	8
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Propiverinehydrochloride

Generic name:	Mictonetten

Ethics review

Approved WMO Date:	09-05-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2004-001243-30-NL
CCMO	NL11578.042.06