# 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

2 - Propiverine hydrochloride in children suffering from overactive bladder and urin ... 2-05-2025

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**

#### **Public**

APOGEPHA Arzneimittel GmbH

Kyffhaeuser Strasse 27 01309 Dresden DE

**Scientific** 

APOGEPHA Arzneimittel GmbH

Kyffhaeuser Strasse 27 01309 Dresden DE

## **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]  $>= ((age +1) \times 30)$  [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