Pharmacokinetics and effects of oral clonidine in children with suspected Growth Hormone deficiency

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(1) To establish the pharmacokinetic profile of clonidine following oral administration in children with suspected GH deficiency. (2) To relate the pharmacokinetics of clonidine to the observed expected (GH-response, cortisol response, depth and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON31430

Source
ToetsingOnline

Brief title
Clonidine in children with suspected Growth Hormone Deficiency

Condition

- Hypothalamus and pituitary gland disorders

Synonym
Growth Hormone Deficiency; Short stature

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Clonidine, Growth Hormone Deficiency, Paediatric, Pharmacology

Outcome measures

Primary outcome

- Pharmacokinetics of clonidine following oral administration

- Growth hormone response following oral administration of clonidine

- Cortisol response following oral administration of clonidine

- Sedation depth following clonidine oral administration, measured with

modified Ramsay Sedation Scale

- Hemodynamic and respiratory parameters (Blood Pressure, Heart Rate,

Transcutaneous oxygen saturation) following oral administration of clonidine

Secondary outcome

- Basal ACTH

- Heart rate variability

- QTc times before and after clonidine administration.

Study description

Background summary

Clonidine is frequently used in a Growth hormone stimulation test in children with suspected growth hormone deficiency. After clonidine (stimulant of GH secretion) administration, serum GH levels are measured until t=150 minutes after clonidine administration. Although it is a widely accepted test which is performed often in pediatric medicine, it does have adverse reactions, mainly hypotension and sedation. In some cases, volume expansion is required to manage hypotensive episodes. It is not known if these adverse reactions are serum clonidine concentration dependent, age related, or if associated hormone deficiencies play a role. A pharmacokinetic profile of clonidine after oral

administration in children has not previously been performed.

Study objective

(1) To establish the pharmacokinetic profile of clonidine following oral administration in children with suspected GH deficiency. (2) To relate the pharmacokinetics of clonidine to the observed expected (GH-response, cortisol response, depth and duration of sedation, hemodynamic parameters) and untoward effects.

Study design

Observational Cohort study

Study burden and risks

Risks: In our opinion no additional risk occurs as a result of study participation. The adverse reactions to clonidine (sedation, hypotension) pose a potential risk, but, clonidine is administered for diagnostic purposes (patient care), not for study purposes. The same goes for the insertion of an intravenous canula.

Burden: The burdensome aspects as a result of study participation are:
- increase in blood sample volume
- More frequent monitoring of hemodynamic parameters (more frequent blood pressure measurement, pulsoximetry, and 3 ECG's)
- Length of stay (including fasting) increased by one hour.

In our opinion this can be viewed as minimal burden.

Note that the informed consent text explicitly states that study participation can also stop 2,5 hours after clonidine administration, the regular duration of the clonidine test.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Written informed consent from parents or legal guardian, in the case of a child aged 12 years or older written informed consent from both parents/legal guardian and the child;
- Patients must be 0-17 years of age;
- Patients must have an indication for a clonidine test to investigate a possible growth hormone deficiency, and this is to be decided by or under supervision of a staff paediatrician, paediatric endocrinologist or fellow

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Catapresan
Generic name:	Clonidine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	22-03-2007
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date:	28-02-2008
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2006-003678-82-NL
CCMO	NL16059.058.07