Intranasal administration of oxytocin in children with Prader-Willi Syndrome. A randomized, open-label, cross-over trial of different treatment regimens of oxytocin administration. Effects on eating behaviour and social behaviour.

Published: 12-10-2016
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To evaluate the effects of long-term intranasal oxytocin on social behaviour in children with PWS and to compare the effects of different doses and frequencies of oxytocin administration

Ethical review	Not approved
Status	Will not start
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Interventional

Summary

ID

NL-OMON43050

Source
ToetsingOnline

Brief title
Intranasal administration of oxytocin in children with PWS

Condition

- Chromosomal abnormalities, gene alterations and gene variants

Synonym
Prader-Willi Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Kind en Groei
Source(s) of monetary or material Support: Stichting Kind en Groei

Intervention

Keyword: Behaviour, Open-label, Oxytocin, Prader-Willi Syndrome

Outcome measures

Primary outcome

The effect of different dosing regimens of intranasal oxytocin administration

on changes in social behaviour assessed by the oxytocin study questionnaire.

Secondary outcome

The effect of different dosing regimens of intranasal oxytocin administration

on changes in:

- Body composition (anthropometric measurements, BMI and DXA-scan)

- Quality of life (DUX25 and DUXPWS)

- Hyperphagia questionnaire (hyperphagia questionnaire Dykens)

- Theory of Mind (TOM test)

- Change in social and eating behaviour (diary)

- fMRI (BOLD responses during a task with food pictures

- Laboratory parameters (oxytocin in saliva and blood)

- Safety parameters (laboratory parameters and medical assessments).

Study description

Background summary

Patients with PWS have behavioural problems and are at risk for morbid obesity.

Several studies demonstrated hypothalamic and oxytocinergic dysfunction in patients with PWS. The number of oxytocin-expressing neurons in the PVN of patients with PWS is significantly decreased with 42%. Recent studies in humans found positive effects of oxytocin on weight balance and social behaviour. The oxytocin system is a promising target for therapeutic interventions, especially in aberration in social function and obesity cotnrol. A pilot study with intranasal oxytocin administration in adults with PWS and our previous study in children with PWS aged 6 to 11 years showed positive effects on social behaviour.
The aim of this study is to investigate the effects of different doses and frequencies of oxytocin administration.

Study objective

To evaluate the effects of long-term intranasal oxytocin on social behaviour in children with PWS and to compare the effects of different doses and frequencies of oxytocin administration

Study design

Randomized cross-over open-label intervention study.

Intervention

Cross-over intervention with intranasal oxytocin in different dosing regimens depending on study group and body surface

Study burden and risks

Burden: administration of intranasal oxytocin once a day, twice a day or every other day during 3-6 months. Three hospital visits with a blood sample, DXA-scan and psychological test and in children >6 years of age a fMRI. A short diary about social and eating behaviour has to be filled out daily by parents.
Risks: we do not expect any side effects or adverse events during oxytocin administration.
Patients and their parents are highly motivated to participate in this study because of the major impact of hyperphagia and social problems on the daily life of patients and their families

Contacts

Public
Stichting Kind en Groei

Westzeedijk 106
Rotterdam 3016AH
NL
Scientific
Stichting Kind en Groei

Westzeedijk 106
Rotterdam 3016AH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Genetically confirmed diagnosis of Prader-Willi syndrome
- Age between 3 and 16 years
- Currently on growth hormone treatment for at least 1 year
- Behavioural problems (for example temper tantrums and autistic behaviour) and/or be in nutritional phase 2b or 3 according to Miller.;For fMRI: age > 6 years

Exclusion criteria

- Severe psychiatric problems
- Non-cooperatieve behaviour
- Allergic reactions or hypersensitivity for oxytocin
- Serious illness
- Cardiac abnormalities
- Extremely low dietary intake or less than minimal required intake acoording to WHO

- Medication to reduce weight (fat)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	44
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Syntocinon
Generic name:	Oxytocin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	12-10-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Not approved

Date:	22-12-2016
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2016-003820-22-NL
CCMO	NL59264.078.16