Randomized, double-blind, placebo-controlled oxytocin trial in children with Prader-Willi syndrome.
Effects on social behaviour.

Published: 04-10-2017
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To evaluate the effects of intranasal oxytocin versus placebo on social behaviour and also on eating behaviour in children with PWS.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Interventional

Summary

ID

NL-OMON44462

Source
ToetsingOnline

Brief title
RCT intranasal administration oxytocin in children with PWS

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Hypothalamus and pituitary gland disorders

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, Oxytocin, Prader-Willi syndrome, RCT

Outcome measures

Primary outcome

Change is social behaviour assessed by:

- Social Responsiveness Scale

Secondary outcome

Change in:

- Clinical Global Impression scale

- Quality of life (DUX25 and DUXPWS)

- Social behaviour (Repetitive Behaviour Scale-Revised, VISK, Oxytocin questionnaire revised)

- Hyperphagia (Hyperphagia questionnaire Dykens)

- Reading the Mind in the Eyes test, child version

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

- Social and food related behaviour (diary)

- Food intake (diary)

- 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 social behaviour and weight balance. The oxytocin system is a promising target for therapeutic intervention, especially in aberration in social function and obesity control. A pilot study with intranasal oxytocin adminstration in adults with PWS showed positive effects on social behaviour, as did our previous study in children with PWS aged 6 to 11 years.

Study objective

To evaluate the effects of intranasal oxytocin versus placebo on social behaviour and also on eating behaviour in children with PWS.

Study design

A randomized, double-blind, placebo-controlled cross-over trial: twice daily intranasal oxytocin or placebo for 3 months each, with a wash-out of 1 month between cross-over.

Intervention

Twice daily placebo and twice daily oxytocin intranasal administration in cross-over design.

Study burden and risks

Burden: administration of intranasal oxytocin or placebo twice daily during a total of 6 months. Six hospital visits in 7 months with questionnaires, four of these visits will include a blood sample, DXA-scan and psychological test. A short diary about social and eating behaviour and food intake has to be filled out by parents daily during 5 days prior to each visit.
Risks: based on literature and our previous experience, 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 social problems and hyperphagia on the daily life of patients and their family.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
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
- Children aged 3 to 10.99 years
- Informed consent
- Currently on growth hormone treatment for at least 1 year
- Behavioural characteristics such as reduced social reciprocity and interaction, repetitive behaviour or temper tantrums, and/or be in nutritional phase 2b or 3 according to Miller (increased interest in food, hyperphagia)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Severe psychiatric problems
- Non-cooperative behaviour
- Allergic reactions or hypersensitivity for oxytocin
- Serious illness

- Cardiac abnormalities
- Extremely low dietary intake or less than required intake according to WHO
- Medication to reduce weight (fat)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-05-2018
Enrollment:	30
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	04-10-2017
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-12-2017
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	EUCTR2017-003423-30-NL
CCMO	NL63031.078.17