Effects of Olanzapine standard oral tablets and orally disintegrating tablets on gut hormones, glucose metabolism and pituitary hormones.

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Novel antipsychotic drugs cause weight gain and type 2 diabetes mellitus in a large percentage of patients. The mechanism of the serious metabolic side effects of these drugs is unclear. Olanzapine orally disintegrating tablet has been found to...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29380

Bron
NTR

Verkorte titel
N/A

Aandoening

engels: antipsychotic drugs, type 2 diabetes mellitus, insulin resistance
Nederlands: antipsychoticum, diabetes mellitus type 2, insuline resistentie

Ondersteuning

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Overige ondersteuning: Lilly, The Netherlands
Dutch Diabetes Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Antrhopometric measurements: BMI, WHR, Body composition.
2. Indirect calorimetry: Resting energy expenditure, respiratory quotient, glucose and fat oxidation.
3. Plasma concentrations: Insulin, glucose, FFA, TG, PYY, PP, GLP-1, GLP-2, OXM, CCK, Ghrelin, ACTH, cortisol, PRL, Adiponectin, Leptin.

Toelichting onderzoek

Achtergrond van het onderzoek

This study was design to study the effect of two different forms of olanzapine, olanzpine standard tablet and olanzapine orally disintegrating tablet, on glucose and lipid homeostasis, gut peptides and various hormones in healthy, normal weight subjects without a positive family history of schizophrenia.

Doel van het onderzoek

Novel antipsychotic drugs cause weight gain and type 2 diabetes mellitus in a large percentage of patients. The mechanism of the serious metabolic side effects of these drugs is unclear. Olanzapine orally disintegrating tablet has been found to cause less weight gain than olanzapine standard oral tablet. We hypothesized that theze two different forms of olanzapine differ in their effect of gut peptide release to explain their dramatically distinct impact on body weight. To further uncover the mechanism through which olanzapine causes weight gain and diabetes mellitus we also studied the impact of olanzapine on spontaneous release of various hormones (i.e. cortisol, prolactin, leptin, adinponectin, insulin, glucose, FFA and TG).

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Subjects are studied after intervention with olanzapine standard tablet (10mg/day for 8 days), Olanzapine orally disintegrating tablet (10 mg/day for 8 days) and without intervention (control). On day 7 subjects were submitted in the clinical reasearch unit, antropometric measures, body composition and fuel oxidation were measured. Blood samples for glucose,

insulin, FFA en TG were drawn every 10 minutes, from 30 min before until 2 hours after dinner and breakfast. Blood samples for gut peptides were drawn every 20-30 minutes from 1 hour before until 4 hours after dinner and breakfast. Samples for determination of ACTH, cortisol, PRL (every 10 min), leptin (every 20 min) and adiponectin (every 30 min) were drawn from 00:00 until 12:hh h. Physical activity was recorded with actimeters for 3 days, during the different experimental conditions.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy men without a positive family history of schizophrenia;

2. Age between 20 and 40 yr.

3. Fasting plasma glucose < 6 mmol/L.

4. BMI between 20 and 26 kg/m2.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Fasting plasma glucose > 6 mmol/L.

2. BMI > 26 kg/m2.

3. Psychiatric disorder and/or use of antipsycotic or antidepressants drugs at present or in the past.

4. Gastrointestinal operations in the past.

5. Any significant chronic disease.

6. Renal, hepatic or endocrine disease.

7. Use of medication known to influence lipolysis and or glucose metabolism.

8. Total cholesterol > 7 mmol/L and or triglycerides > 2 mmol/L.

9. Recent weight changes or attempts to loose weight (>3 kg weight gain or loss, within the last 3 months).

10. Difficulties to insert an intravenous catheter.

11. Smoking (current).

12. Alcohol/drug abuse.

13. Severe claustrophobia.

14. Recent blood donation (within the last 2 months).

15. Recent participation in other research projects (within the last 3 months), participation in 2 or more projects in one year.

16. Extensive sporting activities (more than 10 hours of exercise per week).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	10-04-2006
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	15-03-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL912

Register	ID
NTR-old	NTR936
Ander register	:
ISRCTN	ISRCTN17632637

Resultaten