Raloxifene Augmentation in Patients with a Schizophrenia spectrum Disorder

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Daily treatment with raloxifene 120 milligrams (mg) in addition to antipsychotic treatment improves cognition, reduces psychotic symptoms, increases social and personal functioning, reduces health care costs, as compared to placebo.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27943

Bron
NTR

Verkorte titel
RAPSoDi

Aandoening

schizophrenia, schizophreniform disorder, schizoaffective disorder and psychotic disorder NOS

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcomes are change in symptom severity, measured with PANSS and BNSS and

changes in cognition, measured with BACS.

Toelichting onderzoek

Achtergrond van het onderzoek

Patients with a schizophrenia spectrum disorder experience substantial impairments in multiple domains of everyday life, including the ability to maintain social relationships, sustain employment, and live independently. These problems often persist, even after successful treatment of psychosis. Currently, no consistent evidence exists for the efficacy of interventions to reduce cognitive and negative symptoms, while in fact these are the factors that determine functioning to a great extent.

Premenopausal women with schizophrenia have less psychotic and negative symptoms, and better cognitive and social functioning, in comparison to men and older women. This has been related to protective effects of estrogens in the brain. Administering estrogens has positive effects on psychotic symptoms, but exerts long-term side effects, especially in men.

Raloxifene is a selective estrogen receptor modulator, with a beneficial side effect profile in women and in men. It has been shown to be effective in reducing symptoms in postmenopausal women with schizophrenia. Recently, positive results were found in premenopausal women and in men. It is important to replicate these results in an independent sample and to investigate the effects of raloxifene on functioning.

Hypotheses: Daily treatment with raloxifene 120 milligrams (mg) in addition to antipsychotic treatment improves cognition, reduces psychotic symptoms, increases social and personal functioning, reduces health care costs, as compared to placebo.

Doel van het onderzoek

Daily treatment with raloxifene 120 milligrams (mg) in addition to antipsychotic treatment improves cognition, reduces psychotic symptoms, increases social and personal functioning, reduces health care costs, as compared to placebo.

Onderzoeksopzet

- Baseline

- 2 weeks of treatment (phone call)

- 6 weeks of treatment

- 12 weeks of treatment (end of treatment)

- 6 month follow-up after end of treatment

- 1 year follow-up (phone call)

- 2 year follow-up (phone call)

Onderzoeksproduct en/of interventie

Patients will be randomized 1:1 to either 120mg raloxifene or placebo daily for a period of 12 weeks. Identical tablets will be administered.

Contactpersonen

Publiek

[default]
The Netherlands

Wetenschappelijk

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- A DSM-IV-R diagnosis of: 295.x (schizophrenia, schizophreniform disorder, schizoaffective disorder, or psychotic disorder NOS)

- Capable of understanding the purpose and details of the study in order to provide written informed consent;

- On a stable dose of antipsychotic medication for at least two weeks;

- Age over 18 years.

For female patients:

- Female patients who are sexually active must be willing and capable to use a non-estrogenic contraceptive (intrauterine device, cervical cap, condom or diaphragm) in case of sexual intercourse for the complete duration of the study;

- Female patients with post coital uterine bleeding must have documented normal PAP smear and pelvic examination in the preceding two years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Pre-existing cardiovascular disease;

- History of thrombo-embolic events;

- History of breast cancer;

- Familial tendency to form blood clots (such as familial factor V Leiden);

- Use of vitamin K antagonists;

- Use of cholestyramine or other anion exchange resins;

- Use of levothyroxine or other thyromimetics;

- Hypertriglyceridemia (triglycerides > 3 times the upper limit of normal (ULN));

- Liver function or enzyme disorders (serum bilirubin, alkaline phosphatase (AF), gamma-glutamyl transpeptidase (ã - GT), aspartate aminotransferase (ASAT) or alanine aminotransferase (ALAT) > 3 times the ULN as measured at baseline);

- Severe kidney failure (eGFR <30 ml/min as measured at baseline);

- Use of any form of estrogen, progestin or androgen as hormonal therapy, or antiandrogen including tibolone or use of phytoestrogen supplements as powder or tablet in the past three months.

For female patients:

- Abnormality observed during physical breast examination;

- Pregnancy or breast feeding;

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2016
Aantal proefpersonen:	148
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5550
NTR-old	NTR5672
Ander register	EudraCt : 2015-004483-11

Resultaten

Samenvatting resultaten
Heringa, Sophie M., Marieke JH Begemann, Angelique J. Goverde, and Iris EC Sommer. "Sex hormones and oxytocin augmentation strategies in schizophrenia: A quantitative review." Schizophrenia research (2015).