Raloxifene Augmentation in Patients with a Schizophrenia spectrum Disorder

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27943

Source
NTR

Brief title
RAPSoDi

Health condition

schizophrenia, schizophreniform disorder, schizoaffective disorder and psychotic disorder NOS

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Primary outcomes are change in symptom severity, measured with PANSS and BNSS and changes in cognition, measured with BACS.

Secondary outcome

Secondary outcomes are changes in personal and social performance (measured with PSP), change in severity of thought disorder (measured with TALD), quality of life (measured with EQ-5D), use of healthcare and non-healthcare resources, comorbid depression (measured with BDI), cognitive control (measured with a Stroop Test), language production (measured by analyzing speech samples), hormonal and inflammatory biomarkers, and psychophysiological parameters of basic information processing (i.e. P300 and N100, measured using electroencephalography).

Study description

Background summary

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.

Study objective

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.

Study design

- 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)

Intervention

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

Contacts

Public

[default]
The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2016
Enrollment:	148
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5550
NTR-old	NTR5672
Other	EudraCt : 2015-004483-11

Study results

Summary results
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).