Risperidone versus behaviour therapy in treatment of tics.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23410

Source
NTR

Health condition

tics, tourette, behaviour therapy, exposure and response prevention and habit reversal, risperidone, gedragstherapie, risperidon,

Sponsors and support

Primary sponsor: HSK group, Arnhem
HagaHospital, The Hague
Academic Anxiety Centre Altrecht, Utrecht
Source(s) of monetary or material Support: HSK group, Arnhem
HagaHospital, The Hague
Academic Anxiety Centre Altrecht, Utrecht
NUTS/Ohra

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the Dutch version of the Yale Global Tic Severity Scale (YGTSS).

Secondary outcome

Secondary outcome measures include tic frequency at home and at the institute after 12 weeks, and tic severity and frequency at home and at the institute after 6 and 12 months (follow-up).

General assessment of functioning and quality of life, severity of premonitory sensations, severity of comorbidity and side effects will be measured as well, as are effects during half way of treatment (after 6 weeks). Finally, tic suppressibility during a stressfull task is measured, as well as rates and reasons of dropout.

Study description

Background summary

Gilles de la Tourette syndrome (TS) and chronic tic disorders (CTD) are complex neuropsychiatric disorders that have their onset in childhood and are characterized by tics. Tics are brief, sudden, rapid, recurrent, irresistible, non-rhythmic, stereotyped motor movements or sounds. Usually, they have a childhood onset. At the severe end of the spectrum, tics may have severe impact on mental and physical health including social, educational and occupational functioning (problems in obtaining partners or friends, drop out form school, loss of work productivity). TS is associated with a wide variety of associated behaviours and psychopathologies, e.g. attention deficit hyperactivity disorder (ADHD), obsessive-compulsive disorder (OCD), and autism.

Physically, tics may lead to damage due to the overstraining of muscles or joints. Tics can thus become a severe handicap for patients. Effective treatment of tics at an early stage is essential to improve normal development in children adolescents and quality of life in adults. To date, medication has been the treatment of first choice in managing tic disorders.

Drug treatment of tics is primarily aimed at the dopaminergic and noradrenergic systems. Commonly used agents for reducing tic severity are D2-blocking agents (antipsychotics). Although rather effective in reducing tics, antipsychotics are associated with a wide range of adverse effects including sedation, cognitive dulling, weight gain, depression, anxiety and extrapiramidal side effects. Many patients are reluctant to take antipsychotics and up to 70 percent of patients discontinue medication regimes within the first year.

Recently, several randomised controlled trials in behaviour therapy on tics and TS have shown to be an effective and promising treatment in tic reduction One of these treatments is exposure and response prevention (ERP). The application of ERP to reduce tics is based on the association of unpleasant premonitory sensations, followed by a motor or vocal tic that relieves the sensation. ERP aims at interrupting the association between the PS and the tic, thus preventing the tics to occur. There is support for the hypothesis that, by confronting patients for a prolonged period of time with the sensations (exposure) and resisting the tic

(response prevention), the patients learns to tolerate the unpleasant sensation (habituation). This will lessen the urge or need to give in to the tic, resulting in a reduction of tic behaviour.

To date, no comparative studies between D2-blocking agents and ERP are available in patients with GTS or CTD. It is highly important to know which treatment has the best results, is most cost effective and has the least side effects. The primary aim of the present study is to compare ERP with antipsychotic medication (risperidone) in patients with GTS or CTD.

Study objective

In a randomised, single-blinded, open trial, patients with GTS or CTD will be randomized for medical treatment (Risperidone) or behaviour treatment (exposure and response prevention, ERP).

Risperidone has been shown effective in tic disorders, as well as ERP. ERP has been shown as effective as the more broadly used habit reversal technique. However, effect sizes of ERP were, though not significant, higher than those of habit reversal. In addition, the advantage of ERP over habit reversal is that it tackles all tics at once instead of labour-intensive treating the various tics one by one. This is supported by research data, suggesting that ERP is more effective in case many different tics are present. Effect sizes for ERP were higher than for medication. However, a comparative trial between medication and behaviour therapy has never been conducted, neither for ERP nor for habit reversal. Therefore, the primary aim of the present study is to compare antipsychotic medication treatment (risperidone) with ERP in patients with GTS or CTD. Based on previous studies, we expect ERP to be more effective than medication, also in terms of cost-effectiveness, with less side effects and lower dropout rates. In addition, we expect superior results in the long-term. In ERP, a patient learns a behavioural technique that remains to his disposition at any time in life, while effects of medication disappear when quitting medication. Therefore, if ERP shows to be equally or more effective than antidopaminergic medication, this will strongly influence future treatment regimes in the treatment of tics.

Study design

1. The YGTSS is assessed at week -2, 0, 6, 12, 24 and 52;

2. Tic frequency at home and at the institute after 12 weeks, and tic severity and frequency at home and at the institute at 24 and 52 weeks;

3. The GTS-Quality Of Life is assessed at week 0, 6, 12, 24 and 52;

4. Premonitory Urge for Tics Scale is assessed at week 0, 6, 12, 24 and 52;

5. Side effects are measured in both conditions by the UKU Side Effects Rating Scale and the Extrapyramidal Symptom Rating Scale (ESRS), for measuring parkinsonian and dyskinetic symptoms. In both conditions, side effects are measured every assessment (week 0, 6, 12, 24, 52), besides that, in the medication condition it is used every visit to adjust the dose

accordingly;

6. The ability to suppress tics is tested at pre and post treatment (week 0 and 12), in a tic provocation paradigm.

Intervention

Behaviour therapy versus medication (risperidone). Both are given during 12 weeks.

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Eligibility criteria

Inclusion criteria

1. Patients have to meet DSM-IV criteria for GTS or CTD;

2. Both children and adults are included, ranging from 6 to 65 years of age;

3. Written informed consent by patients, as well as from their parents in case of children (<16) is necessary to participate in the study.

Exclusion criteria

1. Severe major depression, psychosis, addiction, mental deficiency;

2. A known cardiovascular disease, family history of QT prolongation, bradycardia, other

medication known to prolong QT interval;

3. Inability to read/speak Dutch;

4. Patients need to be free of specific tic medication (antipsychotics) for at least four weeks prior to entering the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-08-2010
Application type:	First submission

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	NL2337
NTR-old	NTR2444
Other	METC : 10-016
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A