The European First Episode Schizophrenia Trial (EUFEST): Comparison of outcome in first episode schizophrenia with different low dose antipsychotic drug regimens.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21342

Source
NTR

Brief title
EUFEST

Intervention

Outcome measures

Primary outcome

Retention to allocated study drug, which is the time that the patient stays on the randomised drug within the study dose range. This outcome is assessed at regular time intervals until 12 months after recruitment.

Secondary outcome

At regular time intervals patients are followed-up until 12 months after recruitment: psychopathology (positive symptoms, negative symptoms, depression, agitation-excitement,

disorganisation), side effects (EPS side-effect profile, sexual side effects and weight gain), compliance, social needs, quality of life, substance abuse, neurocognitive functioning, and genetic determinants of response to antipsychotic drugs and natural history of schizophrenia.

Study description

Background summary

In the European First Episode Schizophrenia Trial (EUFEST) we study the effectiveness of antipsychotic drugs in patients with recent onset schizophrenia. EUFEST assesses the effectiveness of a low dose of haloperidol versus regular doses of 4 second generation antipsychotics: amisulpride, olanzapine, quetiapine, and ziprasidone on loss of retention. We focus on the real world treatment of first episode patients by enrolling heterogeneous patient populations, including patients who show comorbid drug abuse or who are aggressive or suicidal or less likely to be compliant with treatment.

The principal investigators are Prof.dr. René S Kahn and Prof.dr. W Wolfgang Fleischhacker.

Study objective

What is the effectiveness of low doses of
haloperidol and regular doses of amisulpride, olanzapine, quetiapine, and ziprasidone on (loss of) one year retention in patients with recent onset of schizophrenia, schizoaffective, and schizophreniform disorder?

Intervention

Drug: Amisulpride 200-800 mg/day

Drug: Haloperidol 1-4 mg/day

Drug: Olanzapine 5-20 mg/day

Drug: Quetiapine 200-750 mg/day

Drug: Ziprasidone 40-160 mg/day

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosis of schizophrenia;

2. Schizophreniform or schizoaffective disorder;

3. Age 18-40 years.

Exclusion criteria

1. A time interval between the onset of positive symptoms (hallucinations and/or delusions) and study entry exceeding two years;

2. Prior use of antipsychotic medication longer than an episode of two weeks in the previous year and/or 6 weeks lifetime;

3. Intolerance to one of the drugs in this study;

4. The presence of one or more of the contraindications against any of the study drugs.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2002
Enrollment:	500
Type:	Actual

Ethics review

Positive opinion

Date:	02-03-2005
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	NL10

Register	ID
NTR-old	NTR25
Other	: N/A
ISRCTN	ISRCTN68736636

Study results

Summary results

1. Kahn RS, Fleischhacker WW, Boter H, Davidson M, Vergouwe Y, Keet IPM, Gheorghe MD, Rybakowski JK, Galderisi S, Libiger J, Hummer M, Dollfus S, López-Ibor JJ, Hranov LG, Gaebel W, Peuskens J, Lindefors N, Riecher-Rössler A, Grobbee DE for the EUFEST study group. Effectiveness of antipsychotic drugs in first-episode schizophrenia and schizophreniform disorder: an open randomised clinical trial. The Lancet 2008; 371: 1085-1097.

Fleischhacker WW, Keet IP, Kahn RS. The European First Episode Schizophrenia Trial (EUFEST): Rationale and design of the trial. Schizophr Res 2005;78:147-56.