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

Submission date
16/05/2005

Recruitment status
No longer recruiting

Registration date
16/05/2005

Overall study status
Completed

Last Edited
19/04/2012

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.eufest.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR25

Study information

Scientific Title
The European study of the effectiveness of haloperidol, amisulpride, olanzapine, quetiapine, and ziprasidone on loss of retention in first episode schizophrenia

Acronym
EUFEST

Study objectives
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?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Schizophrenia, schizophreniform, or schizoaffective disorder

Interventions
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

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Amisulpride, Haloperidol, Olanzapine, Quetiapine, Ziprasidone

Primary outcome measure
Retention to allocated study drug, which is the time that the patient stays on the randomised drug within the study dose range.

Secondary outcome measures
At regular time intervals patients are followed-up until 12 months after recruitment:
1. Psychopathology - positive symptoms, negative symptoms, depression, agitation-excitement, disorganisation
2. Side effects - extrapyramidal symptoms (EPS) side-effect profile, sexual side effects and weight gain
3. Compliance
4. Social needs
5. Quality of life
6. Substance abuse
7. Neurocognitive functioning
8. Genetic determinants of response to antipsychotic drugs
9. Natural history of schizophrenia

Overall study start date
01/12/2002

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Diagnosis of schizophrenia, schizophreniform or schizoaffective disorder
2. Age 18 - 40 years

We will include an unselected group of 500 patients in 13 European countries (Austria, Belgium, Bulgaria, Czech Republic, France, Germany, Italy, The Netherlands, Poland, Romania, Spain, Sweden, and Switzerland) and Israel, with a total of 49 participating sites.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key 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 anti-psychotic medication longer than an episode of two weeks in the previous year and/or six weeks lifetime
3. Intolerance to one of the drugs in this study
4. The presence of one or more of the contra-indications against any of the study drugs

Date of first enrolment
01/12/2002

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Austria

Belgium

Bulgaria

Czech Republic

France

Germany

Israel

Italy

Netherlands

Poland

Romania

Spain

Sweden

Switzerland

Study participating centre
University Medical Centre Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
European Group for Research in Schizophrenia (EGRIS) (Austria)

Sponsor details
Department of Biological Psychiatry
Innsbruck University Clinics
Anichstrasse 35
Innsbruck
Austria
6020

Sponsor type
Research organisation

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca (Netherlands)

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Pfizer (Netherlands)

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Sanofi-Aventis (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/10/2005		Yes	No
Results article	results	29/03/2008		Yes	No
Results article	results	01/06/2009		Yes	No

Results article	results	01/01/2010	Yes	No
Results article	results	01/07/2011	Yes	No