ISRCTN68736636 https://doi.org/10.1186/ISRCTN68736636

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

Contact information

Type(s)
Scientific

Contact name
Dr Han Boter

Contact details
University Medical Centre Utrecht
Department of Psychiatry (A01.126)
P.O. Box 85500
Utrecht
Netherlands
3508 GA
+31 (0)30 250 90 46

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Retention to allocated study drug, which is the time that the patient stays on the randomised drug within the study dose range.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca (Netherlands)

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics, AZ

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, Pfizer Inc

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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
Protocol article	protocol	15/10/2005		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes