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

Submission date	Recruitment status	Prospectively registered	
16/05/2005	No longer recruiting	[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
16/05/2005	Completed	[X] Results	
Last Edited 19/04/2012	Condition category Mental and Behavioural Disorders	[] 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

Contact name

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Contact details

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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

Poland

Romania

Netherlands

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?
<u>Protocol article</u>	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	