European Long-acting Antipsychotics in Schizofrenia Trial EULAST

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON44336

Source
ToetsingOnline

Brief title
EULAST

Condition

- Schizophrenia and other psychotic disorders

Synonym
Schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: EGRIS; Stichting European Group for Research In Psychiatry
Source(s) of monetary or material Support: Stichting EGRIS financiert dit onderzoek

Intervention

Keyword: Compliance Program, Pharmacological Treatment, Schizophrenia

Outcome measures

Primary outcome

Primary outcome is all cause discontinuation (i.e. discontinuation or switching of medication, adding a second antipsychotic agent beyond the allowed limit, patient withdraws consent, patient has missed a monthly visit despite a reminder).

Secondary outcome

Secondary outcome measures includes scores on the Positive and Negative Symptom Scale (PANSS), CGI, Personal and Social Performance scale (PSP), Subjective Wellbeing (SWN), quality of life (EQ-5D), cognitive functioning, prevalence of aggression incidents, resource utilization and safety measures. In a separate protocol with a separate consent form, patients will be asked to provide blood for genetic and immune system analyses.

Study description

Background summary

Schizophrenia is a chronic psychiatric illness with periods of remission and relapse. Patients vary in the frequency and severity of relapse, time until relapse and time in remission. Discontinuation of antipsychotic medication is by far the most important reason for relapse. A possible method to optimize medication adherence is to treat patients with long-term, depot medication rather than oral medication. However, despite its apparent *common sense* this approach has neither been universally accepted by practicing psychiatrists nor unequivocally demonstrated in clinical trials. Therefore, in this study we aim to investigate possible advantages of depot medication over oral antipsychotics

in an independently designed and conducted, randomized, pragmatic trial.

Study objective

Primary objective is to compare all cause discontinuation rates in patients with schizophrenia randomized to either one of the two depot medications (aripiprazole depot or paliperidone palmitate) with patients randomized to either one of the two oral formulations of the same medication (aripiprazole or paliperidone) over an 18 month follow-up period. Secondary objectives include differences in symptom severity, global functioning, quality of life, psychosocial functioning and side-effects, the a-priori opinion of the patients and investigators regarding the comparative values of oral vs. depot medication and safety measures.

Study design

Pragmatic, randomized, open label, multicenter, multinational comparative trial. One month for the medication switch and a follow-up of 18 months. Patients asked to participate but having refused at any time before receiving one dose of trial medication, will be followed with the Clinical Global Impression list (CGI) as closely related to the study schedule as possible, unless they also refuse this.

Intervention

Randomization and medication switch (1:1:1:1) to either paliperidone palmitate or aripiprazole depot or oral aripiprazole or oral paliperidone.

Study burden and risks

Use of the study medication implies that there is a potential for side effects, as all (antipsychotic) drugs carry the risk of side effects. There is no additional risk associated with the study procedures. The pragmatic study design intends to minimize additional time investment from participating subjects. Potential individual benefits are those associated with the closely monitored long term treatment of schizophrenia.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Diagnosis of schizophrenia as defined by DSM-IV-R as determined by the M.I.N.I.plus;2. Age 18 or older. ;3. The first psychosis occurred at least 6 months and no more than 7 years ago.;4. If patients are using an antipsychotic drug, a medication switch is currently under consideration.;5. Capable of providing written informed consent

Exclusion criteria

1. Intolerance / hypersensitivity to both* of the drugs (including active substances, metabolites and excipients) in this study including oral paliperidone and aripiprazole and/or hypersensitivity to risperidone.
2. Pregnancy or lactation.
3. Patients who are currently using clozapine.
4. Patients who do not fully comprehend the purpose or are not competent to make a rational decision whether or not to participate.
5. Patients with a documented history of intolerance to both* of the study medications and/or a documented history of non-response to a treatment with both* study drugs of at least 6 weeks within the registered dose range.
6. Forensic patients.
7. Patients who have been treated with an investigational drug within 30 days prior to

screening.
8. Simultaneous participation in another intervention study (neither medication nor psychosocial intervention).
* If intolerance/hypersensitivity or non-response in the past to one of the compounds is documented, the patient can still participate; however, randomization will take place by blocking that specific compound.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-03-2016
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Abilify
Generic name:	Aripiprazole
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Abilify Maintena
Generic name:	Aripiprazole
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Invega
Generic name:	Paliperidone
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Xeplion
Generic name:	Paliperidone
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-08-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-06-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2014-002765-30-NL
ClinicalTrials.gov	NCT02146547
CCMO	NL49490.041.14