Phase III, multi-center, randomized, 24 week, double-blind, parallel-group, placebo-controlled study to evaluate efficacy and safety of RO4917838 in stable patients with persistent, predominant negative symptoms of schizophrenia treated with antipsychotics followed by a 28 week, double-blind treatment period.

Published: 04-05-2012
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The primary objectives of the study are to:• Evaluate efficacy of 24 weeks treatment with RO4917838 in the PANSS negative symptom factor score in patients with persistent, predominant negative symptoms of schizophrenia treated with antipsychotics.•...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON37510

Source
ToetsingOnline

Brief title
WN25309_Neg

Condition

- Schizophrenia and other psychotic disorders

Synonym
Schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Hoffmann-La Roche
Source(s) of monetary or material Support: Sponsor indicated in section B

Intervention

Keyword: negative symptoms, Phase 3, RO4917838, schizophrenia

Outcome measures

Primary outcome

1. Efficacy (PANSS negative symptoms factor score)

2. Safety (incidence of adverse events)

Secondary outcome

Evaluate efficacy after 24 weeks of treatment with RO4917838 in patients with persistent, predominant negative symptoms of schizophrenia treated with antipsychotics:

• PANSS NSFS in the CFHR1-high subgroup

• personal and social functioning using PSP total score in the all-patient population and in the CFHR1-high subgroup Additional objectives: evaluate the effect of treatment with RO4917838 in patients with persistent, predominant negative symptoms of schizophrenia, in the all-patient population and the CFHR1 subgroups according to patient*s CFHR1 serum at baseline with respect to:

• Other symptom domains of schizophrenia: PANSS total score; PANSS factors: positive symptom, disorganized thought, hostility/excitement, anxiety/depression; PANSS subscales: positive, negative and general psychopathology at week 24; • Clinical Global Impression of severity and improvement on overall and negative symptoms at week 24;

• Safety/tolerability of 52 weeks of randomized study treatment.

Study description

Background summary

Patients with negative symptoms represent a specific subset of patients with schizophrenia. Among patients with schizophrenia, it is estimated that approximately 20% have primary negative symptoms that are sufficiently prominent to warrant clinical attention. Historically, the focus of research into the neurobiology and pathophysiology of this illness has led to treatments with efficacy primarily in positive symptoms. Therefore, there is an urgent need for the development of more effective treatments for negative symptoms of schizophrenia for use in patients treated with antipsychotic drugs.

Study objective

The primary objectives of the study are to:
• Evaluate efficacy of 24 weeks treatment with RO4917838 in the PANSS negative symptom factor score in patients with persistent, predominant negative symptoms of schizophrenia treated with antipsychotics.
• Evaluate safety and tolerability of 24 weeks treatment with RO4917838 in patients with persistent, predominant negative symptoms of schizophrenia treated with antipsychotics.

Study design

Phase III, multi-center, randomized, 24 week, double-blind, parallel-group, placebo-controlled study

Intervention

Treatment Period 1: 24 weeks:
- 5 mg of RO4917838 once a day

- 10 mg of RO4917838 once a day
- Matching placebo once a day

Treatment period 2: 32 weeks:
- 5 mg of RO4917838 once a day
- 10 mg of RO4917838 once a day
- Matching placebo once a day
- Patients assigned to either the 5 mg or 10 mg of RO4917838, may receive placebo during the last 4 weeks of Treatment Period 2

Study burden and risks

RO4917838 treatment has been well tolerated in trials in patients with schizophrenia and healthy volunteers in the dose range proposed. The risk for the individual patient due to treatment with RO4917838 or study-related procedures are considered minimal because of the proposed doses and the careful monitoring of all critical safety parameters. The current risk/benefit profile of the drug justifies continued assessment of RO4917838 in Phase III clinical studies. There is an urgent need for the development of more effective treatments for negative symptoms of schizophrenia for use in patients treated with antipsychotic drugs.

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

• Adult patients, aged 18 years and above
• Diagnosis of schizophrenia of paranoid, disorganized, residual, undifferentiated or catatonic subtype
• Predominant negative symptoms
• With the exception of clozapine, patients are on any of the available marketed atypical or typical antipsychotics (treatment with a maximum of two antipsychotics);For all inclusion criteria, please see protocol.

Exclusion criteria

• Evidence that patient has clinically significant, uncontrolled and unstable disorder (e.g. cardiovascular, renal, hepatic disorder)
• Patient with body mass index (BMI) < 17 kg/m2 or > 40 kg/m2
• Depressive symptoms, defined as a score of 9 or greater on the Calgary Depression Rating Scale for Schizophrenia (CDSS)
• A severity score of 3 or greater on the Parkinsonism item of the ESRS-A (Clinical Global Impression, Parkinsonism).

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-08-2012
Enrollment:	18
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	GlyT1 (1)
Generic name:	GlyT1 (1)

Ethics review

Approved WMO Date:	04-05-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-07-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-11-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-11-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-01-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	06-02-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2010-020467-21-NL
ClinicalTrials.gov	NCT01192906
CCMO	NL40118.042.12