# CAFE Comparison of Atypicals in First Episode of Psychosis

**Purpose**

The purpose of this study is to compare the effectiveness, tolerability, and efficacy of the currently available atypical antipsychotic drugs olanzapine (2.5-20 mg/day), quetiapine (100-800 mg/day) and risperidone (0.5-4 mg/day) in patients with schizophrenia, schizophreniform disorder, or schizoaffective disorder who are experiencing their first psychotic episode.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schizophrenia</td>
<td>Drug: Olanzapine, risperidone</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Psychotic Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental Health</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental Disorders</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sponsor:** AstraZeneca  
**Collaborator:** University of North Carolina  
**Information provided by:** AstraZeneca  
**ClinicalTrials.gov Identifier:** NCT00034892  
**First received:** May 2, 2002  
**Last updated:** January 3, 2013  
**Last verified:** January 2013  
**History of Changes**
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double-Blind
Primary Purpose: Treatment

Official Title: Efficacy and Tolerability of Olanzapine, Quetiapine and Risperidone in the Treatment of First Episode Psychosis: A Randomized Double Blind 52-Week Comparison

Resource links provided by NLM:

MedlinePlus related topics: Mental Disorders Psychotic Disorders Schizophrenia

Drug Information available for: Risperidone Olanzapine

U.S. FDA Resources

Further study details as provided by AstraZeneca:

Study Start Date: March 2002
Study Completion Date: March 2005
Primary Completion Date: March 2005 (Final data collection date for primary outcome measure)

Eligibility

Ages Eligible for Study: 16 Years to 40 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:
- Patients must meet criteria for schizophreniform disorder, schizophrenia, or schizoaffective disorder with psychotic symptoms lasting 1-60 months
- Psychotic symptoms must have persisted at least one month, and not more than 5 years (60 months)
- Patients must have no previous history of drug treatment (greater than a total of 16 weeks) with antipsychotics

Exclusion Criteria:
- Patients with history of psychotic disorder with recovery period of at least 3 months
- Female patients who are pregnant or nursing
- Patients with a known history of mental retardation

**Contacts and Locations**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT00034892

Show 26 Study Locations

**Sponsors and Collaborators**

AstraZeneca

University of North Carolina

**More Information**

No publications provided by AstraZeneca

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):


ClinicalTrials.gov Identifier: NCT00034892  History of Changes
<table>
<thead>
<tr>
<th>Other Study ID Numbers:</th>
<th>5077IL/0114</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study First Received:</td>
<td>May 2, 2002</td>
</tr>
<tr>
<td>Last Updated:</td>
<td>January 3, 2013</td>
</tr>
<tr>
<td>Health Authority:</td>
<td>United States: Food and Drug Administration</td>
</tr>
</tbody>
</table>

Additional relevant MeSH terms:
- Psychotic Disorders
- Mental Disorders
- Schizophrenia and Disorders with Psychotic Features

ClinicalTrials.gov processed this record on March 24, 2015