ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 06/22/2012

ClinicalTrials.gov ID: NCT00681629

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | D1443L00048 |
| Brief Title: | Schizophrenic Patients in Integrated Care ( CARE II ) |
| Official Title: | CARE II - Evaluation of Treatment Outcomes in Schizophrenic Patients Taking Part in the Integrated Care Program - a Single-country, Multi-centre Phase IV Study |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | June 2012 |
| Overall Status: | Terminated |
| Study Start: | July 2008 |
| Primary Completion: | November 2008 [Actual] |
| Study Completion: | November 2008 [Actual] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | AstraZeneca |
| Responsible Party: | Sponsor |
| Collaborators: | |

## Oversight

| | |
|---|---|
| FDA Regulated?: | Yes |
| Applicable Trial?: | Section 801 Clinical Trial? Yes |

| | |
|---|---|
| | Delayed Posting? No |
| IND/IDE Protocol?: | No |
| Review Board: | Approval Status: Approved<br>Approval Number: PVN2941<br>Board Name: Ethik-Kommission der Ärztekammer Hamburg<br>Board Affiliation: Ärztekammer Hamburg<br>Phone: +49 (0) 40-20 22 99<br>Email: ethik@aekhh.de |
| Data Monitoring?: | No |
| Plan to Share Data?: | |
| Oversight Authorities: | Germany: Federal Institute for Drugs and Medical Devices |

## Study Description

| | |
|---|---|
| Brief Summary: | The purpose of the study is to investigate the well-being of schizophrenic patients treated with quetiapine XR combined with participation in the integrated care program compared to a treatment with quetiapine XR alone over a period of 18 month |
| Detailed Description: | |

## Conditions

| | |
|---|---|
| Conditions: | Schizophrenia<br>Schizoaffective Disorder<br>Schizophreniform Disorder |
| Keywords: | Schizophrenia<br>Integrated Care<br>Quetiapine |

## Study Design

| | |
|---|---|
| Study Type: | Interventional |
| Primary Purpose: | Treatment |
| Study Phase: | Phase 4 |
| Intervention Model: | Parallel Assignment |
| Number of Arms: | 2 |
| Masking: | Open Label |

Allocation: Non-Randomized

Endpoint Classification: Efficacy Study

Enrollment: 7 [Actual]

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: Quetiapine XR Alone<br>Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion | Drug: Quetiapine XR<br>400-800 mg, oral, bid<br>Other Names:<br>• Seroquel Prolong |
| Experimental: Quetiapine XR With Integrated Care Program (ICP)<br>Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion | Drug: Quetiapine XR<br>400-800 mg, oral, bid<br>Other Names:<br>• Seroquel Prolong<br>Integrated Care Program (ICP)<br>Integrated care program (ICP), this is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |

## Outcome Measures

[See Results Section.]

## Eligibility

Minimum Age: 18 Years

Maximum Age: 65 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Patients with baseline SWN-K <=70
- Provision of signed informed consent
- Out-patients with schizophrenia, schizophreniform disorder or schizoaffective disorder, severe postpartum depressive disorders with psychotic symptoms and a minimum HAM-D cut off score of 20 points

Exclusion Criteria:

- Evidence of a clinical relevant disease, eg renal or hepatic impairment, significant coronary heart disease, hepatitis B or C, AIDS
- Patients with known cardiovascular disease or other condition predisposing to hypotension or family history of QT prolongation
- Patients who pose an imminent risk of suicide or danger to self or others

## Contacts/Locations

Study Officials: Martin Lambert, MD
Study Principal Investigator
Universitätsklinikum Hamburg-Eppendorf, Martinistr. 52, 20246 Hamburg, Germany

Locations: Germany
Research Site
Berlin, Berlin, Germany

Research Site
Chemnitz, Sachsen, Germany

Research Site
Hamburg, Hamburg, Germany

Research Site
Luneburg, Niedersachsen, Germany

Research Site
Munchen, Bayern, Germany

Research Site
Oldenburg, Niedersachsen, Germany

Research Site
Oranienburg, Brandenburg, Germany

Research Site
Stolberg, Germany

## References

Citations:

Links:

# Study Results

## Participant Flow

| Recruitment Details | Study period July 2008 to November 2008; Centre Dr. Lambert (Hamburg), Centre Dr. Dorn (Berlin) |
|---|---|

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Overall Study

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Started | 5 [1] | 2 [1] |
| Completed | 0 | 0 |
| Not Completed | 5 | 2 |
| Study termination | 4 | 2 |
| Adverse Event | 1 | 0 |

[1] It was planned to recruit 100 patient

## Baseline Characteristics

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Baseline Measures

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone | Total |
|---|---|---|---|
| Number of Participants | 5 | 2 | 7 |
| Age, Customized<br>18-65 years [units: Participants] | 5 | 2 | 7 |
| Gender, Male/Female<br>[units: Participants] | | | |
| Female | 5 | 0 | 5 |
| Male | 0 | 2 | 2 |

## Outcome Measures

1. Primary Outcome Measure:

| | |
|---|---|
| Measure Title | Subjective Well-being in Patients Treated for Schizophrenia, Schizoaffective Disorder, Schizophreniform Disorder, Delusional Disorder or Psychotic Disorder Not Otherwise Specified Using the SWN-K (Subjective Well-being Under Neuroleptics) Scale |
| Measure Description | The SWN-K is comprised of 20 questions, each of which is rated using a 6 point scale ranging from 1 (not at all) to 6 (very much). Possible scores range from 20-120, with higher scores implying higher subjective well-being. |
| Time Frame | 4 months |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

2. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Subjective Well-being Using the SWN-K (Subjective Well-being Under Neuroleptics Scale) Total Score |
| Measure Description | The SWN-K is comprised of 20 questions, each of which is rated using a 6 point scale ranging from 1 (not at all) to 6 (very much). Possible scores range from 20-120, with higher scores implying higher subjective well-being. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

3. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Symptomatic Outcome Using CGI-S (Clinical Global Impression-Schizophrenia) Scale |
| Measure Description | With the CGI-S the rate of the severity of a patient's symptoms (positive, negative, cognitive, depressive and overall) using a scale ranging from 1 (normal, not ill) to 7 (among the most severely ill) is measured - higher scores implying higher severity. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

4. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Symptomatic Outcome Using the PANSS-8 Scales(Positive and Negative Symptoms) Scale Score |
| Measure Description | The schizophrenic symptomatology will be measured by the Positive and Negative Syndrome Scale (PANSS) providing 8 items of which each is rated on a severity scale ranging from 1-7, (1= absent - 7 = extreme severe. higher scores implying higher severity. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

5. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | GAF (Global Assessment of Functioning) Scale Score |
| Measure Description | The "GAF" is a numeric rating scale used by clinicians for assessment of the social, occupational, psychological functioning of adult patients. The scale represents a hypothetical continuum of mental health illness providing a descending scoring code from 100 until 0. Higher scores indicate better patient condition and performance. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

6. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | PSP (Personal and Social Performance) Scale Score |
| Measure Description | The '(PSP" rating scale (100 until 0) used by clinicians for assessment of 4 main domains of functioning in adult patients acc. (a) socially useful activities including work and study, (b) personal and social relationships, (c) self-care, and (d) disturbing and aggressive behavior. Higher scores indicate better patient condition and performance. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

7. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | EQ-5D (European Quality of Life Questionnaire) Score |
| Measure Description | The EQ-5D questionnaire is a generic measure of health status. It defines health in terms of five dimensions:1 (Mobility); 2 (Self-care); 3 (Usual activity); 4 (Pain/Discomfort); 5 (Anxiety/Depression).<br><br>The minimum possible value is 5 (one point for each dimension) and the maximum possible values is 15 (3 points for each dimension). Each dimension has 3 levels of "severity"- "no problems, "some problems" and "extreme problems". Higher scores indicate more problems. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

8. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Vocational Occupational Index "VOC" Score |
| Measure Description | The “VOC” index will assess the following 7 items: 1 fulltime gainful employment, 2 homemaker or student, 3 part-time gainful employment (20 hours per week or less), 4 retired, 5 full or part-time volunteer, 6 on medical or psychiatric leave of absence, 7 unemployed, whether or not expected to work. Results will be descriptively summarized. The VOC index will be completed at each visit. Difference from baseline of the index will be derived at each assessment |
| Time Frame | Up to 18 months (V1 Day 1, V2 Month 1, V3 Month 3, V4 Month 6, V5 Month 12, V6 Month 18) |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

9. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Assess Quality of Life Levels Using the Q-LES-Q-18 (Quality of Life Enjoyment and Satisfaction) Questionnaire |
| Measure Description | Q-LES-Q-18 will allow to generate a general QoL-index which will be used for the analysis and is defined as the average of the single scores for all 18 items. Scoring will be carried out from 1-5 per item (never / rarely / sometimes / frequently / all the time). Results will be descriptively summarized. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

10. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Assess Quality of Life Levels Using the RSM Scale (Riedel-Spellmann-Musil) Scale |
| Measure Description | The '(RSM" is a new 36-item measure validated to assess the "QoL" in different dimensions of schizophrenic patient treated with antipsychotics. It will be rated on a four-point Likert scale (not / rather not / rather yes / yes) by the patient and the investigator. The total score ranges from min. 0 to max. of 108. Higher scores indicate higher "QoL". |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

11. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Assess Patient Engagement to Therapy Using the SES Scale (Service Engagement Scale) |
| Measure Description | The 'SES" is a 14-item measure consisting of statements that assess the client specific engagement with services. It will be rated on a four-point Likert scale (not at all / rarely / sometimes / most of the time) by the investigator. The total score ranges from min. 0 to a max. of 42. Higher scores indicate lower engagement. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

12. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Assess Compliance/Medication Adherence Using the MARS Scale (Medication Adherence Rating Scale) |
| Measure Description | The 'Medication Adherence Rating Scale' (MARS) is a reliable and valid self-reporting tool for investigation of the compliance in psychiatric patients also recognizing the complexity of compliance behaviour. 10 questions on medication attitude have to be answered by 'yes' or 'no' (8 times 1= no and Yes = 0 and twice 1= no, Yes =1). Results will be descriptively summarized. Summarized results minimum 0: low medication adherence, maximum 10: high medication adherence. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

13. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Evaluate the Level of the Patients' (Subjective) Satisfaction Using the CSQ-8 Scale (Client Satisfaction Questionnaire) |
| Measure Description | The 'CSQ-8" is a brief, self-administered method to monitor the consumer's satisfaction with services in outpatient psychotherapy, showing high internal consistency. It is identified as a core subset of the general CSQ covering 8 Likert-type items with four response choices where '1' indicates the lowest and '4' the highest degree of satisfaction. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

14. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Assess Health Economy Improvements in Terms of a Reduction in Treatment Costs and Loss of Productivity by Determination of the Total Cost by Number of Days With Hospitalization |
| Measure Description | Any hospitalisation days in inpatients units and emergency ward stays will be recorded. At each hospitalisation, the number of days will be computed and at each visit, the cumulative total number of days will be used to calculate total costs. As higher the number of hospitalisation days as higher the costs per patient. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

15. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Assess Health Economy Improvements in Terms of a Reduction in Treatment Costs and Loss of Productivity by Determination of the Total Number of Days the Patient Was Not Able to Work or go to School or Complete Routine Daily Activities |
| Measure Description | The number of lost work days, lost school days or days without completing routine daily activities will be evaluated. With any number of lost workdays or lost school days or without completing routine daily activities, the costs will increase and the productivity will decrease. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

16. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Assess Health Economy Improvements in Terms of a Reduction in Treatment Costs and Loss of Productivity by Determination of the Need for Any Additional Antipsychotic Medication |
| Measure Description | Concomitant psychotropic drugs will be coded (ATC = Drug code) to allow a comparison of the number of drugs used per ATC class and per treatment visit. The drugs used will be listed by keeping their brand name for allowing to translate them into costs. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

17. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Evaluate Safety and Tolerability by Evaluation of Weight/Waist Circumference |
| Measure Description | Measuring of weight and waist circumference in centimeter. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

18. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Evaluate Safety and Tolerability by Evaluation of Laboratory Tests |
| Measure Description | Measuring of: B-Haemoglobin (g/dl), B-Haematocrit(%), B-Erythrocyte count(pl), B-Leucocytes count (nl), B-Platelet count(nl), Complete blood count (nl), B-Leucocytes differential count (%), B-HbA1c(%), S-ALAT (U/l), S-ASAT (U/l), S-GGT (U/l), P-Glucose (fasting)(mh/dl), S-prolactin level (ng/ml), S-Pregnancy test (IU/l), Qualitative analysis of urine with Stix®,Urine pregnancy. Comparing results with standard values. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

19. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Evaluate Safety and Tolerability by Evaluation of Concomitant Medication |
| Measure Description | Listing of all concomitant medication to show the efficacy and safety. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

20. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Evaluate Safety and Tolerability by Evaluation of the Incidence of Adverse Events |
| Measure Description | Listing of all adverse event or SAE´s to show the safety and tolerability. |
| Time Frame | 4 month |
| Safety Issue? | No |

Analysis Population Description

No data were reported as no participants completed the study

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Measured Values

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

## Reported Adverse Events

| | |
|---|---|
| Time Frame | [Not specified] |
| Additional Description | [Not specified] |

Reporting Groups

| | Description |
|---|---|
| Quetiapine XR With Integrated Care Program (ICP) | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion.<br><br>Integrated Care Program (ICP) is a legally based integrated care program covered by a contract according to §§ 140 a-d SGB-V (SGB: social security code); The ICP is not exclusively designed for this phase IV trial. Participation in the ICP is possible anytime for each patient in whom the services are covered by the individual health insurance. |

| | Description |
|---|---|
| Quetiapine XR Alone | Oral administration as 200 mg and 300 mg tablets allowing flexible dosing in 100 mg steps. Once daily in the evening. On day 1: 300 mg quetiapine XR, on day 2 : 600 mg, from day 3 onwards 400 to 800 mg at the centre-specific investigator´s discretion |

Serious Adverse Events

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 0/5 (0%) | 0/2 (0%) |

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

| | Quetiapine XR With Integrated Care Program (ICP) | Quetiapine XR Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 2/5 (40%) | 1/2 (50%) |
| Gastrointestinal disorders | | |
| Dry Mouth [A] † | 1/5 (20%) | 0/2 (0%) |
| Nausea [A] † | 1/5 (20%) | 0/2 (0%) |
| General disorders | | |
| Fatigue [A] † | 1/5 (20%) | 1/2 (50%) |
| Investigations | | |
| Weight Increased [A] † | 0/5 (0%) | 1/2 (50%) |
| Musculoskeletal and connective tissue disorders | | |
| Neck Pain [A] † | 0/5 (0%) | 1/2 (50%) |
| Psychiatric disorders | | |
| Abnormal Dreams [A] † | 1/5 (20%) | 0/2 (0%) |
| Suicidal Ideation [A] † | 0/5 (0%) | 1/2 (50%) |

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 10.0

## Limitations and Caveats

The study was stopped due to poor enrollment and no data analysis was performed.

## More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Site has to inform sponsor about a publication at least 60 day in advance and 10 days before submission of an abstract or presentation. Change requests by the sponsor are recognized unless the scientific character or the objectivity is on risk. If the sponsor plans a patent application the publication has to be postponed up to 120 days.

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