Declared, B. P. Rathour: None Declared, K. Mistry: None Declared, M. Dutta: None Declared, A. Ramaraju: None Declared, S. Mangalwedhe: None Declared, S. G. Goyal: None Declared, G. Kulkarni: None Declared, A. Mukhopadhyay: None Declared, P. Chaudhary: None Declared, G. T. Harsha: None Declared, M. Parikh: None Declared, S. Dey: None Declared, S. Sarkhel: None Declared, N. Jyothi: None Declared, A. Kumar: None Declared, N. Sooch: None Declared, A. Shetty Employee of: Sun Pharma, S. Saha Employee of: Sun Pharma, P. Devkare Employee of: Sun Pharma, A. Shetty Employee of: Sun Pharma, D. Patil Employee of: Sun Pharma, P. Ghadge Employee of: Sun Pharma, A. Mane Employee of: Sun Pharma, S. Mehta Employee of: Sun Pharma

EPV0250

Efficacy and Safety of Lumateperone compared to Quetiapine in Indian patients with Bipolar II depression: A subgroup analysis based on age

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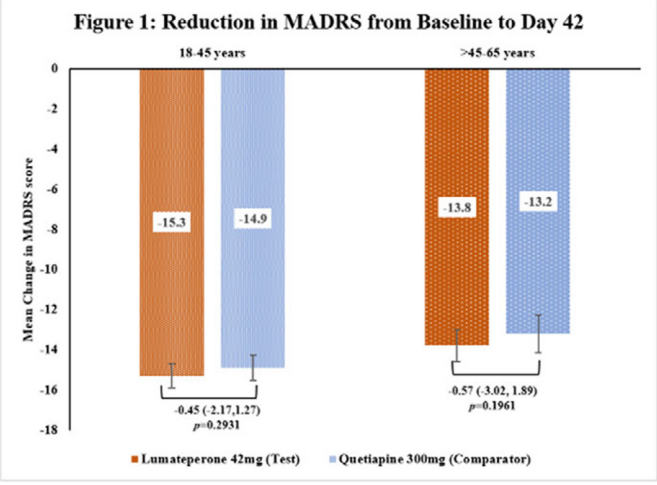
Introduction: Lumateperone, an atypical antipsychotic drug, has a dual mechanism of action by combination of activity at central serotonin (5-HT2A) and dopamine (D2) receptors.

Objectives: This subgroup analysis of an Indian Phase 3 study was conducted to evaluate the efficacy and safety of Lumateperone 42mg compared to Quetiapine 300mg in treatment of Bipolar II depression when stratified based on age (18-45, >45-65).

Methods: The phase-III, randomized, multi-centric, assessor-blind, parallel-group, active-controlled, comparative, non-inferiority study included Indian patients with Bipolar II depression with moderate severity having a Montgomery-Asberg depression rating scale (MADRS) score ≥20 and Clinical global impression–bipolar version–severity (CGI-BP-S) score ≥4. The study was conducted after receiving regulatory and ethics committee approvals. The patients were randomized (1:1) to either receive Lumateperone 42mg [Test] or Quetiapine 300mg [Comparator] for 6 weeks. The patients were stratified based on age: Subgroup 1 [S1]: 18-45 years and Subgroup 2 [S2]: >45-65 years. For efficacy outcomes MADRS score, CGI-BP-S (total score, depression subscore and overall bipolar illness subscore), and Quality of life enjoyment and satisfaction-short form questionnaire (Q-LES-Q-SF) score were evaluated and for safety outcomes treatment emergent adverse events (TEAEs) were assessed. [Clinical trial registration: CTRI/2023/10/058583]

Results: This subgroup analysis included 462 patients, out of which 320 in S1[Test=159; Comparator=161] and 142 in S2[Test=72; Comparator=70]. The baseline demographic characteristics were comparable in between treatment arms across subgroups. The primary endpoint of reduction in MADRS score from baseline to Day 42 in Test arm was non-inferior to Comparator arm in both subgroups [Figure 1] as the upper 95% CI was below the predefined margin of 3.0. The reduction of CGI-BP-S (total score, depression subscore and overall bipolar illness subscore) from Day 14 to Day 42 were comparable in both Test and Comparator arms in both subgroups. The improvement in Q-LES-Q-SF score from baseline to Day 42 were comparable in both Test and Comparator arms in both subgroups. The incidence of TEAEs were comparable in both treatment arms [S1: Test=31.4% and Comparator=36.6%; S2: Test=41.7% and Comparator=32.9%] and no serious adverse events were reported.

Image 1:



Conclusions: This subgroup analysis demonstrated that Lumateperone 42mg is non-inferior to Quetiapine 300mg in treatment of Bipolar II depression as assessed via MADRS score from baseline to Day 42, irrespective of age of the patients and both treatments were found to be well tolerated. Hence, Lumateperone can be considered as valuable treatment option in management of Bipolar II depression.

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S. G. Goyal: None Declared, G. Kulkarni: None Declared, A. Mukhopadhyay: None Declared, P. Chaudhary: None Declared, G. T. Harsha: None Declared, M. Parikh: None Declared, S. Dey: None Declared, S. Sarkhel: None Declared, N. Jyothi: None Declared, A. Kumar: None Declared, N. Sooch: None Declared, A. Shetty Employee of: Sun Pharma, S. Saha Employee of: Sun Pharma, P. Devkare Employee of: Sun Pharma, A. Shetty Employee of: Sun Pharma, D. Patil Employee of: Sun Pharma, P. Ghadge Employee of: Sun Pharma, A. Mane Employee of: Sun Pharma, S. Mehta Employee of: Sun Pharma

EPV0251

A triptorrelin-induced manic episode: a case report

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Introduction: Gonadotropin-releasing hormone (GnRH) agonists are the recommended treatment in non-localized prostate cancer. Psychiatric disorders induced by GnRH agonists are rare, but they can include depressive symptoms, irritability, anxiety and auditory hallucinations. Manic episodes are even less frequent.
Objectives: With this case, we aim to remind, that although rare, affective episodes, particularly manic episodes, can occur with the use of GnRH agonists, namely triptorelin.
Methods: Case report.
Results: A 72-year-old man, without relevant psychiatric medical history was admitted to the in-patient unit because of a Manic Episode. It was characterized by hyperfamiliarity, pressured speech, coprolalia, accelerated thinking, flight of ideas and a euphoric/irritable mood. He also had delusional ideas of grandiosity and persecution, centered on his family.
The most common organic causes were ruled out, but it stood out that this patient was under treatment with a long-acting injectable formulation of triptorelin because of a recently diagnosed prostate adenocarcinoma.
Antipsychotics and mood stabilizer drugs were used, but symptoms were only partially remitted. Therefore, we decided to stop all medications, including triptorelin, and a gradual improvement in manic symptoms was observed.
Conclusions: Mood disorders can be an adverse effect of the use of GnRH agonists and, although the expected response to the psychotropic drugs was not observed, symptoms eventually remitted when the effect of Triptorelin wore off, about three months after patient's last dose.
The literature recommends the use of mood stabilizers in the presence of affective symptoms after treatment with GnRH agonists, but some cases may need the GnRH agonists to be discontinued.

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EPV0252

Feasibility of Actigraphy in a Longitudinal Study of Patients with Bipolar Disorder

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Introduction: Bipolar disorder (BD) is a severe psychiatric disorder characterized by recurring acute mood episodes of depression or euphoria, alternating with phases of euthymia, with a prevalence in the general population of 2%. Individuals with BD frequently experience disruptions in sleep and circadian rhythms, present during both euthymic and acute mood phases, yet these disturbances are challenging to measure objectively. Tracking these changes can offer insights into the progression of BD and potential risk for mood relapse. Actigraphy, a non-invasive monitoring technique, holds promise for capturing objective, real-world data on sleep and circadian patterns, thereby aiding in the assessment and management of BD.
Objectives: This study aims to assess the feasibility of using actigraphy as a tool for monitoring sleep-wake patterns and physical activity levels in patients with BD over a longitudinal period.
Methods: Within The Bipolar Exposome-Gene Interaction Naturalistic (BEGIN) project we conducted a longitudinal study of individuals diagnosed with BD using wrist-worn actigraphy (Withings Steel HR) to collect data on daily activity and sleep parameters over 12 months. Feasibility was evaluated based on participant adherence to the actigraphy protocol, data quality, technical challenges, and acceptability by patients and clinicians.
Results: Results indicated satisfactory enrolment rate (N=87, 66.4%) in the study and compliance with the use of actigraphy (N= 59, 67.8%). The main reasons for not accepting the study were non-response to contacting efforts (43.2%) and lack of interest (24.3%). No age differences were found between individuals who accepted the study and those who did not. A high retention rate was obtained (N=80, 92%) with the main reason for drop-off being the perception of intense follow-up within the study. Regarding actigraphy, younger individuals were more likely to accept its use ($t = -2.066$, p-value = 0.043) and the main reason for non-adherence was rash development (42.9%). Patient feedback highlighted the ease of use and minimal disruption of daily life.
Conclusions: In conclusion, actigraphy is a feasible and effective tool for continuous monitoring in BD, offering potential for improving the understanding of mood episodes and treatment efficacy in future studies. Further exploration of actigraphy in larger cohorts and its integration with other physiological measures is recommended.

Disclosure of Interest: None Declared