

**Introduction:** Long-acting injectable antipsychotics (LAIs) have emerged as a new therapeutic option to treat patients suffering a psychotic disorder. To date, there is a lack of studies regarding safety and clinical use pattern of LAIs in pregnant women.

**Objectives:** Provide evidence and real world clinical data of pregnant women with schizophrenia who have been treated with long-acting aripiprazole monohydrate (aripiprazole once monthly [AOM] condition) during their pregnancy.

**Methods:** Descriptive real-world clinical experiences of pregnant women in treatment with AOM. The information was obtained by reviewing electronic medical records and by direct clinical observation management.

**Results:** The first six case-series describing the pregnancy course of women with schizophrenia treated with AOM. All of them remained psychopathologically stable through pregnancy, and their infants became healthy with normal developmental milestones (Table 1).

**Table 1.** Clinical characteristics of six case-reports.

Mothers	1	2	3	4	5	6
Maternal/Pregnancy outcomes						
Age(years)	35	29	35	31	38	30
Diagnosis	Schizophrenia	Schizophrenia	Schizophrenia	Schizophrenia	Schizophrenia	Schizophrenia
AOM(mg/days)	400-300	400-300	400-300	160	300	400
Type of delivery	Eutocic.	Eutocic, preterm	Eutocic	Eutocic	Eutocic	Eutocic
Neonatal outcomes						
Weight(grams)	3300	1800	3140	3102	2940	3400
Gender	Female	Female	Male	Male	Male	Male
Developmental Abnormalities (years)	No(3)	No(2)	No( 0.17)	No(2)	No(2)	No(1.5)

**Conclusions:** The favorable results in this case-series suggest that despite the lack of evidence on reproductive safety and treatment with AOM during pregnancy, this therapeutic option should be considered in pregnant women with schizophrenia. However, further research on the use of long-acting antipsychotics in pregnant women is needed.

**Disclosure:** No significant relationships.

**Keywords:** Long-acting injectable antipsychotics; Pregnancy; schizophrenia; second-generation antipsychotics

## EPP0016

### Effectiveness of oral versus long-acting antipsychotic treatment early-phase schizophrenia patients: an open-label randomized trial

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**Introduction:** 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.

**Objectives:** 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 19 month follow-up period.

**Methods:** Pragmatic, randomized, open label, multicenter, multinational comparative trial consisting of a 19 month treatment period. Patients aged 18 years or older, having experienced the first psychosis 1-7 years ago, currently meeting DSM-IV-R criteria for schizophrenia. Patients are randomized 1:1:1:1 to paliperidone palmitate, aripiprazole depot, oral aripiprazole or oral paliperidone. The primary outcome is all cause discontinuation.

**Results:** In the Intent to Treat sample (n=511), no difference was found in time to ACD between the combined oral and combined depot treatment arms, nor between the four individual treatment arms.

**Conclusions:** Even though the scientific evidence comparing oral and depot medication has been inconsistent, most studies were conducted in rigorous clinical settings, which may have biased those results. In contrast, given the pragmatic, open label design of the current trial, the results may be more representative of common daily practice.

**Disclosure:** No significant relationships.

**Keywords:** long-acting antipsychotics; oral antipsychotic; all-cause discontinuation; schizophrenia

## EPP0017

### Lifestyle intervention on psychotherapy and exercise and their effect on physical and psychological health in outpatients with schizophrenia spectrum disorders. A pragmatic clinical trial.

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**Introduction:** Patients with Schizophrenia Spectrum Disorders (SSD) often lead unhealthy lifestyles with higher prevalence of obesity and unfavourable cardiometabolic parameters with less life expectancy and often worse quality of life compared with general population.

**Objectives:** Evaluate the effectiveness of a combined intervention of exercise and psychoeducation in 48 SSD outpatients with metabolic syndrome (MetS), treated with second-generation antipsychotics and also aimed to explore if the effect persisted in a long-term follow-up of 24 months.