36th ENTIS Conference 11th – 14th Sept 2025
ARISTOTLE UNIVERSITY'S RESEARCH DISSEMINATION CENTER (KEDEA)
THESSALONIKI, GREECE
E-Poster 65

SAFETY OF ARIPIPRAZOLE DURING THE FIRST TRIMESTER OF PREGNANCY: A PROSPECTIVE COHORT STUDY

Azienda Ospedaliero Universitaria Careggi
UNIVERSITÀ DEGLI STUDI FIRENZE NEUROFARBA DIPARTIMENTO DI NEUROSCIENZE, PSICOLOGIA, AREA DEL FARMACO E SALUTE DEL BAMBINO

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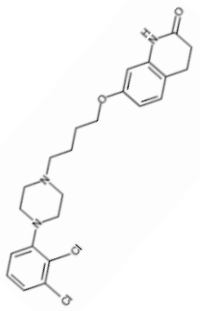
Background

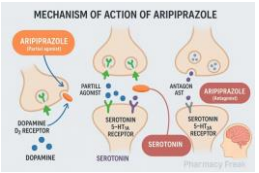
Atypical antipsychotic use has increased among women of childbearing age, despite limited pregnancy safety data. Aripiprazole may be preferable during pregnancy due to its lower association with metabolic issues and obesity, which is beneficial since psychiatric patients have higher gestational diabetes rates. Previous studies show reassuring results but are limited by small sample sizes, prompting this prospective observational cohort study on first-trimester aripiprazole safety.

ARIPIPRAZOLE is a chiral quinolone derivative, third-generation antipsychotic class, partial agonist of D2/5HT1a receptors. EMA approval: 06/04/2004



Indications:

- Treatment of schizophrenia in individuals 15 year-old and older
- Treatment of moderate to severe manic episodes in bipolar I disorder
- Prevention of a new manic episode in adults who have experienced predominantly manic episodes and where these episodes responded to treatment with aripiprazole



ARIPIPRAZOLE IN PREGNANCY

Aripiprazole is less frequently associated with metabolic dysregulation compared to other atypical antipsychotics [L'Italien et al., J Clin Psychiatry, 2007

Estimated transplacental passage at approximately 54.67% [Windhager et al., J Clin Psychopharmacology, 2014]

The most frequently prescribed antipsychotic during pregnancy, along with quetiapine [M. P. Freeman et al., Arch Womens Ment Health, 2021]

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NEUROFARBA
DIPARTIMENTO DI NEUROSCIENZE, PSICOLOGIA, AREA DEL FARMACO E SALUTE DEL BAMBINO

Study goal

To assess the safety and teratogenic risk of aripiprazole taken during the first trimester of pregnancy through a prospective observational cohort study

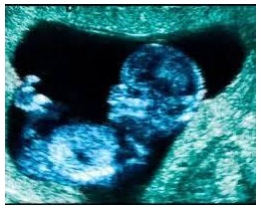
Study design

Prospective observational cohort study: 3 cohorts of pregnant women who contacted the Florence TIS from 01/01/2012 to 12/31/2023:

- Study cohort: exposure to aripiprazole
- Control cohort: exposure to antipsychotics (olanzapine/quetiapine)
- Control cohort: exposure to quetiapine or olazanzapine (data not shown)

INCLUSION CRITERIA

Exposure to aripiprazole/olanzapine/quetiapine between the 4th and 12th weeks of pregnancy
Gestational age at the time of the first call < 12 weeks



EXCLUSION CRITERIA

TORCH infections
Patients with active substance use disorder (DUS)
Alcohol consumption > 1 standard drink (UA) per day
Women who smoked until the end of pregnancy > 20 cigarettes per day
Exposure to known teratogenic drugs
Pre-pregnancy Body Mass Index (BMI) > 39
Age > 40 years
Medically assisted reproduction
Contact with TIS after 12 weeks
Aripiprazole use after 12 weeks
Drop out
Non-Caucasian women and women with non-Caucasian partners
Multiple pregnancies

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Azienda Ospedaliero Universitaria Careggi
Università degli Studi Firenze NEUROFARBA Dipartimento di Neuroscienze, Psicologia, Area del Farmaco e Salute del Bambino

Study goal

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Study design

Prospective observational cohort study: 3 cohorts of pregnant women who contacted the Florence TIS from 01/01/2012 to 12/31/2023:
- Study cohort: exposure to aripiprazole
- Control cohort: exposure to
- Control cohort: exposure to quetiapine

QUESTIONNAIRE
- Maternal age
- Gravidity: number of previous conceptions
- Parity: number of previous deliveries
- Past and recent medical history
- Pharmacological history
- Folic acid supplementation
- Exposure to ionizing radiation
- Cigarette smoking
- Alcohol
- Psychotropic substances
- Occupation/professional exposure
- Education

FOLLOW-UP
3 months after the estimated date of delivery

-Gestational age at the time of delivery
-Type of delivery
-Neonatal birth weight
-Head circumference (HC)
-Apgar score (AS)
-Neonatal pathologies
-Congenital defects

EVALUATION OF PREGNANCY OUTCOMES
-Spontaneous Abortion/Miscarriage(SAB)
-Intrauterine Fetal Demise/Stillbirth (IUFD)
-Elective Termination of Pregnancy (ETOP)
-Therapeutic Termination of Pregnancy (TTP)
-Small for gestational age infants (SGA)
- Major congenital malformations (MCM)

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RESULTS

24312 women called the Florence TIS 2012-2023

661 pregnancy exposerd to:
- ariprazole
-olanzapine
- quetiepaine

228 pregnancies met inclusion criteria

102 pregnancy exposed to ariprazole

64 pregnancy exposed to olanzapine

62 pregnancy exposed to quetiapine

	ARIPRAZOLE	OLANZAPINE /QUETIAPINE	RR
Miscarriage	19,6%	18,2%	1.0 (95% IC 0.73-1.5)
ETOP	5,8%	7,3%	0.89 (95% IC 0.47-1.7)
MCM (on 76 and 93 live births respectively)	2,6%	4,4%	1.22 (95% IC 0.18-8.48)
Preterm	14,4%	8,6%	1.3 (95% IC 0.87 - 2.0)
SGA	9,3%	11%	0,85 (95% IC 0,34- 2,08)

CONCLUSIONS

The study found **no evidence of teratogenic potential for aripiprazole**.
However, the relatively small sample size prevents conclusive determination of absolute safety, which would require a sample size two orders of magnitude larger.