Long-term Antipsychotic Pediatric Safety trial

(LAPS)

What are we studying?

The purpose of this study is to learn more about the long-term effects for children and teens who are taking either aripiprazole (Abilify®) or risperidone (Risperdal®). Risperidone and aripiprazole are FDA-approved for children for the treatment of schizophrenia, specific bipolar disorders, and irritability associated with autistic disorder. Aripiprazole is also FDA-approved for the treatment of Tourette's disorder.

In this research project we will track changes to weight in children ages 3 to 17 years old who are taking risperidone or aripiprazole. The study will also look at risks associated with weight gain, such as abnormal blood tests, and high blood pressure. Depending on the study results, the US Food and Drug Administration (FDA) may use these results to improve the drug labels that guide how risperidone and aripiprazole are prescribed to children in the US.

Who can participate?

We are looking for volunteers male and female,

- 3 -17 years old
- Currently taking (or expecting to take) **aripiprazole (Abilify®)** or **risperidone (Risperdal®)**
- Planning to be on this medication for at least six months
- Willing to permit the Study Doctor to consult with your Prescribing Doctor
- Willing to attend five semi-annual study visits at UMMS

How will participants be compensated?

Compensation will be provided for time and travel.
For more information, contact CANDI at 774-455-4100 or ChildResearch@umassmed.edu.
WIRB Protocol #20180459

Investing in the future...helping children and families.