

# Participate in Research

## Metformin for Motor and Cognitive Improvement in Children with Cerebral Palsy: A Feasibility Study



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**TO ASK QUESTIONS OR FIND OUT IF YOUR CHILD IS ELIGIBLE, PLEASE CONTACT:**

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### Do you have a child diagnosed with cerebral palsy?

Consider participating in our clinical trial for a study drug called Metformin!

#### What is this study about?

We are doing a clinical trial to see if taking the study drug Metformin for 16 weeks plus physiotherapy can improve motor and thinking skills compared with physiotherapy alone in children with cerebral palsy.

This study will be done at two different places in Toronto: Holland Bloorview Kids Rehabilitation Hospital (Holland Bloorview) and the Hospital for Sick Children (SickKids).

#### Who can participate?

We are looking for children between 5-12 years of age who:

- Have cerebral palsy with stiffness on both sides of the body
- Gross Motor Function Classification System (GMFCS) Level of II – V
- Born prematurely (less than 37 weeks gestation)
- Able to communicate (verbal or non-verbal)
- Meet other safety and eligibility criteria

#### What's involved?

- Each child will be in the study for 40 weeks (10 months)
- Being randomly assigned (50/50 chance) to get either Metformin or a placebo
- Taking the study pill every day for 16 weeks (about 4 months)
- Sharing some medical information

##### At Holland Bloorview:

- Physiotherapy twice a week for 16 weeks (45 minutes per session)
- Examinations with a study doctor and 3 blood draws

##### At SickKids:

- MRI pictures of your child's brain (1 hour per session)
- Tests to measure thinking ability (~ 90 minutes)
- Answering quality of life questionnaires (30-40 minutes)

#### Potential Risks?

- Metformin is generally a safe drug, but does have some side effects associated with it such as diarrhea, stomach pain, feeling weak, and muscle pain
- Blood draws may cause some pain, light-headedness, and bleeding or bruising
- Possible fatigue when completing questionnaires