Essai Clinique

Généré le 21 mai 2024 à partir de

Titre	Phase III Randomized Double-blind Placebo-controlled Trial of Metformin for Cognitive Recovery and White Matter Growth in Paediatric Medulloblastoma Patients
Protocole ID	Met Med Can
ClinicalTrials.gov ID	NCT05230758
Type(s) de cancer	Cerveau (SNC)
Phase	Phase III
Type étude	Clinique
Médicament	Chlorhydrate de metformine versus placebo
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL CHUL ET CENTRE MERE-ENFANT SOLEIL 2705 boulevard Laurier, Québec, QC, G1V 4G2
Ville	
Investigateur principal	Dre Valérie Larouche
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Statut	Actif en recrutement
Date d'activation	07-09-2022
But étude	The efficacy of treatment with metformin for promoting cognitive recovery and brain growth in children/adolescents treated for medulloblastoma will be investigated in a multi-site Phase III randomized double-blind placebo-controlled parallel arm superiority trial. Specifically, in children/adolescents aged 7 years to 17 years and 11 months who have completed treatment for medulloblastoma, is oral administration of metformin for 16 weeks associated with greater improvement of cognitive function and brain growth compared to placebo administered for 16 weeks?

Critères d'éligibilité	In order to be eligible to participate in this study, an individual must meet all of the following criteria:
	• No less than 3 weeks after completion of primary therapy for medulloblastoma
	• Age 7 years to 17 years and 11 months at the time of enrollment
	• Either declare English (or French in accepting sites) as their native language or have had at least two years of schooling in English (or French in accepting sites) at the time of consent
	• Able to swallow tablets either whole, crushed or via a feeding tube and be willing to adhere to the study intervention regimen
	• Meet criteria for normal organ function requirements as described below:
	  • Normal renal function defined as: Estimated glomerular filtration rate (eGFR) > 75ml/min/1.73m²
	  • eGFR is calculated using the Schwartz formula: eGFR (mL/min/1.73m²) = (0.41 × height in cm) / creatinine in mg/dL
	  • Normal liver function defined as:
	  • Serum glutamic-oxaloacetic transaminase (SGOT) (AST) <1.5 institutional upper limit of normal (ULN) for age and gender
	  • Serum glutamic pyruvic transaminase (SGPT) (ALT) <1.5 institutional ULN for age and gender
	  • Total bilirubin <1.5 institutional ULN for age and gender
	• Informed consent (and assent, where applicable) will be obtained from the participants and/or their legal guardian(s) by study team members delegated to consent for this study

Critères d'exclusion	Participants who meet any of the following criteria will not be eligible to take part in the trial: • Unable to participate in MRI without sedation • Standard score of less than 60 for full scale IQ on the Wechsler Abbreviated Scale of Intelligence, Second Edition (WASI-II) (for English speaking participants) or pro-rated IQ score on the Wechsler Intelligence Scale for Children, Fifth Edition (WISC-V) (for French speaking participants) at Screening visit • Have a known hypersensitivity to metformin hydrochloride • Have unstable and/or insulin-dependent (Type 1) diabetes • Have a history of hypoglycemia after 2 years of age • Have been diagnosed with acute or chronic metabolic acidosis and/or lactic acidosis or have a lactate level greater than 5 mmol/L at the Screening visit • Have a history of renal disease or renal dysfunction • Have a history of congestive heart failure requiring pharmacologic treatment (including the use of diuretics) within two years prior to study entry • Currently taking part in a cognitive rehabilitation intervention study • Treatment or planned treatment involving diuretics • Current or planned treatment with cationic drugs excreted by the kidneys (e.g. amiloride, cimetidine, digoxin, morphine, nifedipine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, and vancomycin) • Current or planned treatment with concomitant medications with potential unacceptable interaction with metformin including topiramate, lamotrigine, levetiracetam, beta blockers, angiotensin-converting enzyme (ACE) inhibitors, glycopyrrolate, and carbonic anhydrase inhibitors, or at the discretion of the Site PI or delegate for medications with potential interactions such as sertraline, lansoprazole and omeprazole. • Pernicious anemia (according to results of the Screening visit blood draw) • Current use of metformin hydrochloride • Any condition or diagnosis, that could in the opinion of the Site PI or delegate interfere with the participant's ability to comply with study instructions, might confound the interpretation of the study results, or put the participant at risk