Treatment of down syndrome using haloperidol

CLINICAL RESEARCH FACILITY APPLICATION

Q1 Details of Main Contact:

Title & Name: “ Haloperidol in Down Syndrome” and Sivaram Kumar Sivalingam Pandiyarajan

Q2 Study title Treatment of Down Syndrome using Haloperidol

Q3 Please provide an abstract or brief synopsis of the proposed study (Max 250 word

Haloperidol is an antipsychotic drug which exhibits high affinity towards dopamine D receptor antagonism. It also shows a slow receptor dissociation kinetics which is sim phenothiazines. The drug is used in the treatment of schizophrenia were polymorphi the dopamine receptor genes showed the presence of psychotic phenomena or aggr behavior. Down syndrome (DS) increases the risk of Alzheimer’s disease (AD) by 15% people who live 40 years are long. Problems related to behavior are not a general iss other syndromes associated with intellectual disability. 30% of children with DS have mental illness. Anxiety and depression in early adulthood may develop for the peopl DS. Studies indicate that polymorphisms in dopamine receptor D_1 (DRD1) and dopa receptor D_3 (DRD3) genes in late-onset AD exhibit symptoms of psychotic phenome aggressive behavior in people. Haloperidol suppresses the ionic imbalance by blocki beta-amyloid-induced elevation of calcium in Alzheimer cells which showed a signific decrease in calcium cells. Studies also indicate that the symptoms of attention-defic hyperactivity disorder (ADHD) in DS also showed the effects of executive function in with DS about the dopamine receptor DRD4 gene linked to ADHD in people with DS. it is hypothesized that haloperidol can be used in the treatment of Down syndrome.

Indicate your Word Count (Max 250 words). 215

Q4 Please outline what question(s) the study is designed to answer/primary measure outcome (Max 150 words).

The primary outcome of the study is to reduce the relapse of patients into psychosis down syndrome (DS). Reduction of relapse in DS due to psychotic breakdown which similarly as in schizophrenia which indicates the activity of haloperidol in the preven diseases prognosis. During the study, details for questions such as the " how the effe haloperidol action on dopamine receptors reduce disease prognosis of DS," " What is mechanism of action of haloperidol in the treatment of DS?", " Does haloperidol prev prognosis of DS by intervening the mechanism involved in Alzheimer's disease (AD) Attention-deficit hyperactivity disorder (ADHD)?", Etc.

Indicate your Word Count (Max 150 words). 105

Q5 Indicate clearly how you will perform the study (include methods, materials, num patients, demographics, statistics and all other matter that you consider important) 1500 words).

Haloperidol is an ethically approved drug which is already on the market and used fo treatment of schizophrenia, acute psychosis, Tourette syndrome, bipolar disorder, et haloperidol is ethically approved direct administration of the drug to the patients wh down syndrome (DS) can be performed, and observation study can be conducted. Hu materials such as primary cell culture and organotrophic culture from a patient are r for the detailed understanding of the mechanism of action involved in the treatment using Haloperidol. The mechanism of action should be compared with the Alzheimer disease (AD) and Attention-deficit hyperactivity disorder (ADHD) to analyze the effec

Researchers have estimated that out of 1200 people one will suffer from DS in the U States this includes children, teens, and adults. Children with DS usually do not have retardation and a psychiatric disorder. 18% to 38% of children with DS currently hav possibility for the prevalence of the neurobehavioral and psychiatric disorder. During the research studies conducted regarding DS, determined that a pre-pubertal onset for children with DS presenting in the post-pubertal period which is the unique vulne period for specific psychiatric disorders.

The Study Design is performed by randomized allocation where a parallel interventio model of drug assignment is proposed. The subject, investigator and outcome asses masked from the drug and placebo treatment using a double-blind method to achiev efficiency and less interference. The primary purpose remained to be the treatment disease. The inclusion and exclusion criteria for the participants for involving the stu neglected of age (18 to 64 years) and sex (Male, Female, and others) as a criterion. inclusion criteria, the patient should be primarily diagnosed with DS and should be hospitalized with Standard Trisomy 21, Translocation, and Mosaicism DS. The patien have been diagnosed with the illness for at least one year and should have gone psychological evaluations. At the most, the patient should be able to drop off of any antipsychotic medication for a period.

There are two phases in the study of Haloperidol on DS. The DS outpatients who mee criteria for inclusion and exclusion is allowed to enter the Phase 1. A flexible dose of Haloperidol 1-5mg is given to the patients for 20 weeks of open acute treatment pha oral dose of 1 mg of Haloperidol is given daily, where the dose is titrated until the op dose is reached with an increase of 1 mg per titration. The optimal dose is fixed base optimal trade-off between side effects and efficacy. Phase 1 looks for patients who m criteria for clinical response and another exit the protocol and are treated with alter

medications openly. The patients who responded well in phase 1 are taken into Phas
where the random assignment of placebo-controlled continuation trial takes place fo
weeks. Based on the severity and presence of psychosis the randomization is stratifi
where half of the patients takes haloperidol, and other patients receive a placebo. Th
Patients who relapse with psychosis during Phase B will exit the protocol and receive
extensive treatment.

To attain the statistical significance and to achieve a normal distribution the alpha va
set as 0. 1 and small minimum sample size of 99 participants is required to pilot this
Repeated measures ANOVA is to be conducted at three major time-points in the wee
week 20 and baseline. This analytic strategy is to be used to measures the efficacy a
side effects, global cognition, and activities of daily living.

Indicate your Word Count (Max 1500 words). 603

Q6 Indicate clearly the need to work with human materials for this research in terms
ethical approvals (Max 200 words).

Haloperidol is an ethically approved drug which is already on the market and used fo
treatment of schizophrenia, acute psychosis, Tourette syndrome, bipolar disorder, et
Researchers have estimated that out of 1200 people one will suffer from Down synd
the United States this includes children, teens, and adults. Hence, the need of drug f
treatment of down syndrome (DS) is raising. Since haloperidol is ethically approved
administration of the drug to the patients who have DS can be performed, and obser
study can be conducted. The study requires less attention of rules and guidelines for
issues. Since there is no proper animal model for DS and obtaining, culturing, and
preservation of primary cell culture and organotrophic culture from patients with DS
Hence the need for human clinical trials is necessary for testing the drug “ haloperid

the treatment of DS.

Indicate your Word Count (Max 200 words). 147