

## What happens during the study?

You and your child will first need to meet with a member of the study team at a research center convenient to you. Here the study team member will ask questions and perform some tests and procedures (see below) to make sure your child is eligible for the study.

If your child is accepted, you will need to make 11 more visits to your study center. Your child will be given a capsule to swallow every day during the 12 weeks of the study. There will also be five sessions of talking therapy (brief psychosocial interventions) with a study team member throughout the study. There will also be a follow-up visit once the study is complete, bringing the total to 13 visits over 16 weeks.

Your child will be required to perform certain tests and procedures during these study visits. These include, among others:

### General health checks

### Height and weight checks

**Blood and urine samples** – four blood tests in total

**Electrocardiograms (ECGs)** – painless procedures that measure your heartbeat and rhythm

**Self-assessment questionnaires** – your child writes about how they are feeling during the study

**Depression symptom assessments** – conducted by the study doctor

For more details on the study program, please see the Kites study fact card.

If your child completes the study and your doctor thinks it is in their best interest, you may be invited to participate in further visits

Contact details: 403-210-6904



THE MATHISON CENTRE  
for MENTAL HEALTH RESEARCH & EDUCATION



UNIVERSITY OF  
CALGARY

LU\_12709A/10A\_EN\_v4.2\_3 Mar 2016\_Leaflet\_English for Canada\_v4.3\_27 July 2016

# Is your child troubled by depression?



  
An **ADVANCE** study

## What is Kites?

If your child is affected by depression and still experiencing its symptoms – you may be interested in the Kites study.

Kites, an ADVANCE study, is an international clinical research study that will evaluate the safety and effectiveness of an investigational medicinal product in treating depression in children and young people between the ages of 7 and 17.

## What is a clinical research study?

Clinical research studies, also known as clinical trials, are conducted to determine whether or not a drug is safe and effective in treating a particular condition.

## What is an investigational medicinal product?

An investigational medicinal drug is one that is being evaluated in a clinical research study before it can be approved by a regulatory body for use in humans.

## What is an antidepressant?

An antidepressant is a type of medication that may help improve the symptoms of depression. Antidepressants have to be prescribed by a doctor. There are currently many approved antidepressants for adults, but very few for use in children and young people.

## Who can take part?

The Kites study team is looking for children and young people who are:

- aged between 7 and 17
- diagnosed with major depressive disorder (MDD)
- being treated for MDD as an outpatient by a clinician
- available to take part in the study for up to 16 weeks

If your child meets these criteria and you would like to find out more about the Kites study, please contact your local study team or talk to your doctor.

## Why take part?

Taking part in a clinical research study does not mean your child's condition will improve; there are potential risks in the form of side effects as well as potential benefits. By taking part in the Kites study, your child will be contributing to the development of an investigational drug. The potential benefits of participating may include study-related professional care and the chance to learn more about your child's condition.

Ethics ID# REB16-0708 and REB16-0904

This study has been approved by the University of Calgary Conjoint Health Research Ethics Board