

# A study about Autism

## Why have you been asked to help?

You are being asked to take part in this study because you have autism. We would like to see if a new test medicine is safe and if it can help autistic people.



Some people will get the test medicine, and others will get a pretend one. You won't know which one you have been given.



## Important things to know...

You can say 'No' or 'Yes' to be part of this study.

No one will be mad or sad if you say 'No'.

If you say 'Yes', you can always say 'No' later.

We will still take good care of you no matter what you say.

You can take your time to choose "Yes" or "No"

You can ask as many questions as you want, any time.

## What will happen to me during this study?

The study doctor and nurse will give you a check-up to see if you can be a part of the study.

If you take part, the study doctor and team will need to:

- Ask you how you are feeling
- take some blood to make sure you are ok.
- Ask you to pee in a cup.
- Check your height and weight, and your health.
- check how well your heart is working using an arm wrap and small sticky pads.
- Ask your parent(s)/guardian(s) some questions about you.
- Ask you to do picture tests on a computer. They are fun to do.
- Give your parent(s)/guardian(s) the medicine you have to take at home.



### What will I need to do?

If you take part in the study, it will take up to **4 months**. You will come to see us with your parent or guardian.

-you will visit us at the hospital **5 times**

- and you will have **2 phone calls**.



Your parent(s)/guardian(s) will give you the medicine, when you awake, **once a day**, 1 or 2 tablets, every day for **12 weeks**.

You can take the medicine with any food or drinks

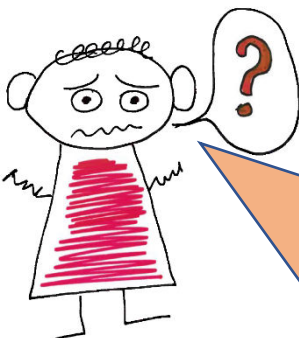


### Will any part of this study hurt?

We will use a needle to take your blood, it might hurt or make your skin red and swollen. To help with the hurt, we can use a special cream.

For checking your heart, we will place some sticky pads on your arms, legs, and chest. They might make your skin a little red or itchy.

You might feel a little unwell when you take the study medicine. You could have pain in your head, or you may find difficult to sleep when you go to bed. If you do not feel well, tell your parent/guardian.



### My study doctor:

Name: \_\_\_\_\_

Phone contact:  
\_\_\_\_\_



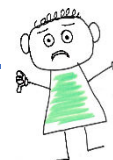
### Can this study help me?

We don't know if the study medicine will make you better or not.

The study may help doctors know what medication to give to other autistic children/adults in the future.



**Assent statement**



**Please initial each box**

I understand what will happen to me if I take part in this research.	
My mum, dad, or person taking care of me knows about this study and they want me to be in it if I want to.	
I know I can stop whenever I like.	
This study has been explained to me.	
I and my mum, dad or person taking care of me can ask the study doctor any question at any time.	
I will get a copy of this form.	
I agree to take part in this research study.	

My name: \_\_\_\_\_

Date: \_\_\_\_\_



<b>Name of Study:</b>	An Exploratory, Multicenter, Randomized, double-blind, placebo controlled study evaluating the effect and safety of pitolisant in children and adolescents with autism spectrum disorders.
<b>Study Number:</b>	P21-01
<b>Study Doctor &amp; Research Site Address:</b>	<i>[Principal Investigator First and Last Name]</i> <i>[Site Name and Address]</i> <i>Phone number + [Office Hours Tel]</i> to be added by study site
<b>Patient ID</b>	

**Statement of person conducting assent discussion:**

- I have explained all aspects of the research study to the participant to the best of his ability to understand.
- I have answered all of the participant’s questions relating to this research.
- The participant agrees to be in the research.
- The participant’s decision to enrol is voluntary.
- The study doctor and study team agree to respect the participant’s physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

\_\_\_\_\_  
Printed Name of Person Conducting Assent Discussion

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Person Conducting Assent Discussion

Note:

While children/adolescents may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent to or dissent from participation. Out of respect for children/adolescents as developing persons, they should be asked whether or not they wish to participate in the research study.

(When completed: 1 original to be filed in the Investigator Study File (ISF), 1 to be kept in the medical records, 1 for the participant)