IN DOCTOR PAINAWAY’S STUDY...

HIYA. MY NAME IS DOCTOR PAINAWAY. I’M RESEARCHING HOW WE CAN DRIVE AWAY THE PAIN THAT YOUNG PEOPLE LIKE YOU MIGHT FEEL.

THIS IS MY ASSISTANT BUNSEN, A MAN OF FEW WORDS.

JUST ONE, IN FACT.

GABA.

BUNSEN SAYS “HI”.

NORMALLY, OUR BODY FEELS PAIN FOR A SIMPLE REASON...

AS I BRING MY HAND CLOSE TO THE FLAME...

OUCH! SEE? OUR BODY QUICKLY REACTS TO PREVENT IT GETTING TOO HURT.

BUT WHEN THE PAIN IS TOO STRONG AND DOESN’T GO AWAY, WE NEED TO ACT.

GABAAAA!

OH, DEAR!

SORRY, BUNSEN. THIS MEDICINE ONLY WORKS IF YOU’VE BEEN IN PAIN FOR A LONG TIME.

YOU’LL BE FINE SOON, DON’T WORRY.

GABAAAA!

BUNSEN SAYS “THANK YOU”.

GABA GABA.
The medicine has been used a lot, but we don't yet know if it will work for children like you. Which is why we're asking you to take part to the GABA study.

GABA GABA?

The GABA study is just a way to understand how well the medicine works with children.

Here, let me show you.

A group of children will take some syrup and a few drops three times a day.

Every day, they will tell their parents how strong their pain is. This will let the doctors know if the medicine is working or if they need more.

We really hope the pain will get better, but your body takes time to react to the medicine so it can take a couple of weeks.

So it's important to always tell the truth about the pain you're feeling.

But how do you measure pain?
GOOD QUESTION, YOUNG LADY!

YOU CAN MEASURE PAIN BY PUTTING A CROSS ON ONE OF THESE LITTLE FACES.

BUNSEN WILL SHOW YOU HOW THIS WORKS.

ARE YOU SURE YOU WANT TO DO THIS, BUNSEN?

YOU'RE SO BRAVE...

GABA GABA!

IF YOU ARE A BIT OLDER, YOU CAN ALSO MEASURE PAIN BY SAYING HOW MUCH IT HURTS FROM 0 TO 10.

0 MEANS YOU'RE FEELING GREAT, AND 10 MEANS IT HURTS AN AWFUL LOT.
WHAT ELSE WILL HAPPEN IN THE STUDY?

1. THE FIRST PART OF THE STUDY WILL BE 1 TO 2 WEEKS LONG, WITH 2 VISITS.

On your first visit, the doctor will give you a check up, take some of your blood and use a little machine to find out how well your heart is working.

For 3 days after that you won’t take any medicine, except for fast pain relief medicines if you really need them.

2. THEN THE SECOND PART OF THE STUDY WILL BE 15 WEEKS LONG, WITH 8 VISITS.

The doctor will give you the drops and syrup to take three times a day.

The doctor will also take some of your blood once or twice. On one visit, you will spend 4-5 hours in the hospital, so he will take blood over a longer period.

But it only stings for a moment!

3. THE THIRD AND LAST PART OF THE STUDY WILL BE FROM 1 TO 5 WEEKS LONG, WITH 2 MORE VISITS.

You will take less and less of the medicine as you approach the end of the study.

Your doctors will make sure everything is okay and ask you how you feel.

It’s important to tell them the truth. Isn’t it, Bunsen?

GABA GABA GABA GABA...

I REST MY CASE.
THESE ARE YOUR 12 VISITS OVER THE 18-22 WEEKS OF THE STUDY.

ARE YOU READY?

SET?

GO!

THE RULES OF OUR STUDY:
- 94 CHILDREN, UNDER 18 YEARS OF AGE
- 18-22 WEEKS IN LENGTH
- 3 DAYS WITH ONLY MEDICINES FOR FAST PAIN RELIEF
- 15-19 WEEKS TAKING THE STUDY MEDICINE
- 2 OR 3 BLOOD SAMPLES

BUNSEN SAYS YOUR DOCTOR MIGHT VISIT YOU A FEW EXTRA TIMES.

AND THAT THIS IS PERFECTLY NORMAL.
WHAT TESTS WILL YOU HAVE TO DO?

YOUR DOCTOR WILL EXAMINE YOU TO CHECK YOU’RE OKAY.

YOUR DOCTOR WILL TAKE SOME OF YOUR BLOOD 2 OR 3 TIMES.
WHY SHOULD I TAKE PART? AND WHAT ARE THE DOWNSIDES?

If you feel too much pain, your doctors may give you more medicine. But if you take a lot of the medicine, you may get what we call side effects.

You may feel less pain than before.

Which means you can have more fun. More games, more school, more everything.

You may help other children who also need to take medicine for pain.

You may have fewer problems than with your current medicines.

Your doctor will always keep an eye on you and make sure that the study is not dangerous. Always tell your parents or your doctor how you are feeling, so that we can help.

You will need to go to the hospital 8 times, have a few tests and take your medicines.

If you feel too much pain, your doctors may give you more medicine. But if you take a lot of the medicine, you may get what we call side effects.
THAT’S WHY IT’S IMPORTANT TO ALWAYS TRUTHFULLY TELL US HOW YOU FEEL.

IF YOU FEEL ANYTHING STRANGE HAPPENING, TELL YOUR PARENTS OR LET YOUR DOCTOR KNOW STRAIGHT AWAY.

YOUR DOCTOR WILL TELL YOU WHAT TO DO.

WHAT ARE THESE SIDE EFFECTS?

DRY MOUTH

MOOD CHANGES

NAUSEA

RESTLESSNESS

SLEEPINESS

DIZZINESS

TROUBLE GOING TO THE LOO

GABA!

GABA!
DO I HAVE TO TAKE PART TO THE STUDY?

GOODNESS, **NO!**
YOU CAN DO AS YOU WISH.

IT’S NORMAL TO HAVE THE SIDE EFFECTS?

**ABSOLUTELY.** SOME PEOPLE HAVE THEM, AND SOME PEOPLE DON’T.

WHO WILL KNOW I’M TAKING PART?

ONLY **YOU, YOUR PARENTS** AND YOUR **DOCTOR**.

WHAT IF I CHANGE MY MIND DURING THE STUDY?

YOU CAN **LEAVE** AT ANY TIME. YOUR DOCTOR WILL **CONTINUE HELPING YOU** AS HE DID BEFORE.

BUT IF YOU ARE WORRIED, REMEMBER YOUR DOCTOR WILL ALWAYS BE KEEPING AN EYE ON YOU.

THE CHOICE IS YOURS TO MAKE.
GAPP – GAbapentin in Paediatric Pain

COORDINATOR
Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF)

GABA-1 Clinical Trial
EudraCT Number: 2014-004851-30

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PHArmaceutical Research Management SRL (PHARM)

Randomized, double-blind, double-dummy, active controlled, multicentre, non-inferiority phase III study to compare the pharmacokinetic, efficacy and safety of gabapentin liquid formulation to tramadol in children from 3 months to less than 18 years of age experiencing moderate to severe chronic neuropathic or mixed pain.

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