FREE TO FLY
LIVING WITHOUT PAIN

GAPP - GAbapentin in Paediatric Pain

GABA-1 12-17 years

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FREE TO FLY – Living Without Pain

Chronic pain, which is pain that lasts more than three months, severely limits people's lives. Help can come in the form of drugs to ease the pain, called **analgesics**.

However, the effectiveness of analgesics can decrease over time, leaving some patients without pain relief.

Using several analgesics can help manage chronic pain better. A drug given to adults called **Gabapentin** is safe and can ease certain types of pain, but is **not yet approved** for people **under 18 years of age**.

A group of doctors and researchers have planned a new Gabapentin study for young patients, the **GABA-1 study**. During the study all measures will be taken to ensure **patient's safety.** If the results are positive, Gabapentin will be approved for all children and teenagers who need chronic pain relief.

The information in this booklet will help you decide if you want to take part in the study. Your doctor will answer any questions and help you make your choice, along with your parents.

This choice is yours to make.

If you don't feel like taking part, or you wish to leave the study at any point, **you are free to do so**. Your doctors will **continue to help you** as best they can.

THE GABA-1 STUDY

To verify that Gabapentin is effective and safe in young patients, researchers will **compare it** to another analgesic already used in children called **Tramadol.**

To do so, 94 patients under 18 years of age from Albania, Estonia, France, Germany, Greece, Italy and Netherlands will be randomly **split in two groups.**

Also, you probably noticed that your pain can **increase** or **decrease.** For instance, your mood can affect how you feel, and it's possible that knowing which medicine you're taking could change the way you experience your pain.

How can we avoid this influence?

Easy. **You won't know** which of the two medicines you are taking.

This is how the study works

Over the course of 18-22 weeks, you will take **two different preparations** 3 times a day (morning, afternoon and evening).

One preparation will contain an **analgesic** (Gabapentin or Tramadol). The other will contain a **placebo**, a substance that looks, smells and tastes like a medicine, but is not a medicine at all.

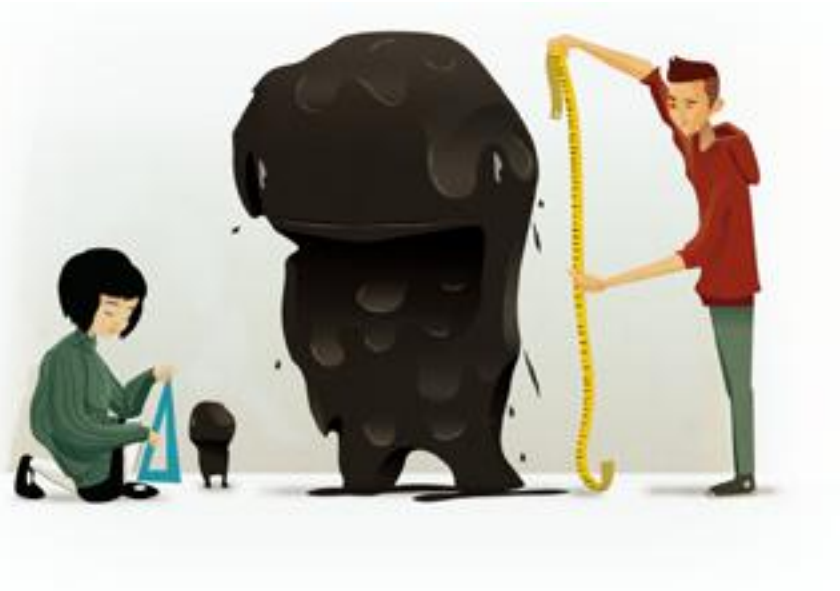
Group 1 will take
a syrup with Gabapentin (analgesic)
and drops with a placebo

Group 2 will take
a syrup with a placebo
and drops with Tramadol (analgesic)

Neither you nor your doctor will know which group you are in. So the way you are feeling won't be influenced by knowing which medicine you are taking.

And yet you will **always be taking a drug** to reduce your pain.

Each day you will measure your pain on a **scale from 0 to 10**. You and your parents will write this number in a diary and eventually give it to your doctor.



You should remember that your pain **may not decrease right away**. It may take a **couple of weeks**.

Gabapentin is very effective in adults, but there is **no absolute certainty** that it works as well in teenagers. Your body might react **differently**.

Being **honest** is crucial. Tell your doctor and your parents exactly how you feel, without diminishing or exaggerating it.

1 Study, 3 Phases

Phase 1

1–2 weeks

2 visits

screening, assessment and interruption of the medicines you are currently taking

Your doctor will **examine you**, give you a few **tests** and **stop the medicines** you are currently taking (except for paracetamol and ibuprofen).

On visit 1, you will be given a **general check-up**, your **heart** will be tested with an ECG, and a sample of your **blood** will be collected. Female patients will have a pregnancy test and will be monitored for pregnancy for the rest of the study.

On visit 2, all participants will be given a **general check-up**, and female patients will also do a **pregnancy test**.

Phase 2

15 weeks

8 visits

treatment

You will start taking the **study medicine.**
Over the course of 3 weeks, the dosage will be raised or adjusted in order to be **more effective.**

The **correct dosage** will then be kept over the course of the following 12 weeks.

You will talk to the doctor 3 times over the **phone.**

The remaining 5 visits will be **in person** at the hospital. During 1 or 2 of these visits, samples of your **blood** will be collected.

Phase 3

1–5 weeks

2 visits

discontinuation of study treatment and final check-up

The doctor will slowly **decrease** your medicine.
This may take up to 4 weeks.

You will have one visit at the **hospital.**

A week after you take your last dose of medicine, you will have one final visit over the **phone.**

The GABA-1 study will last **between 18 and 22 weeks.**

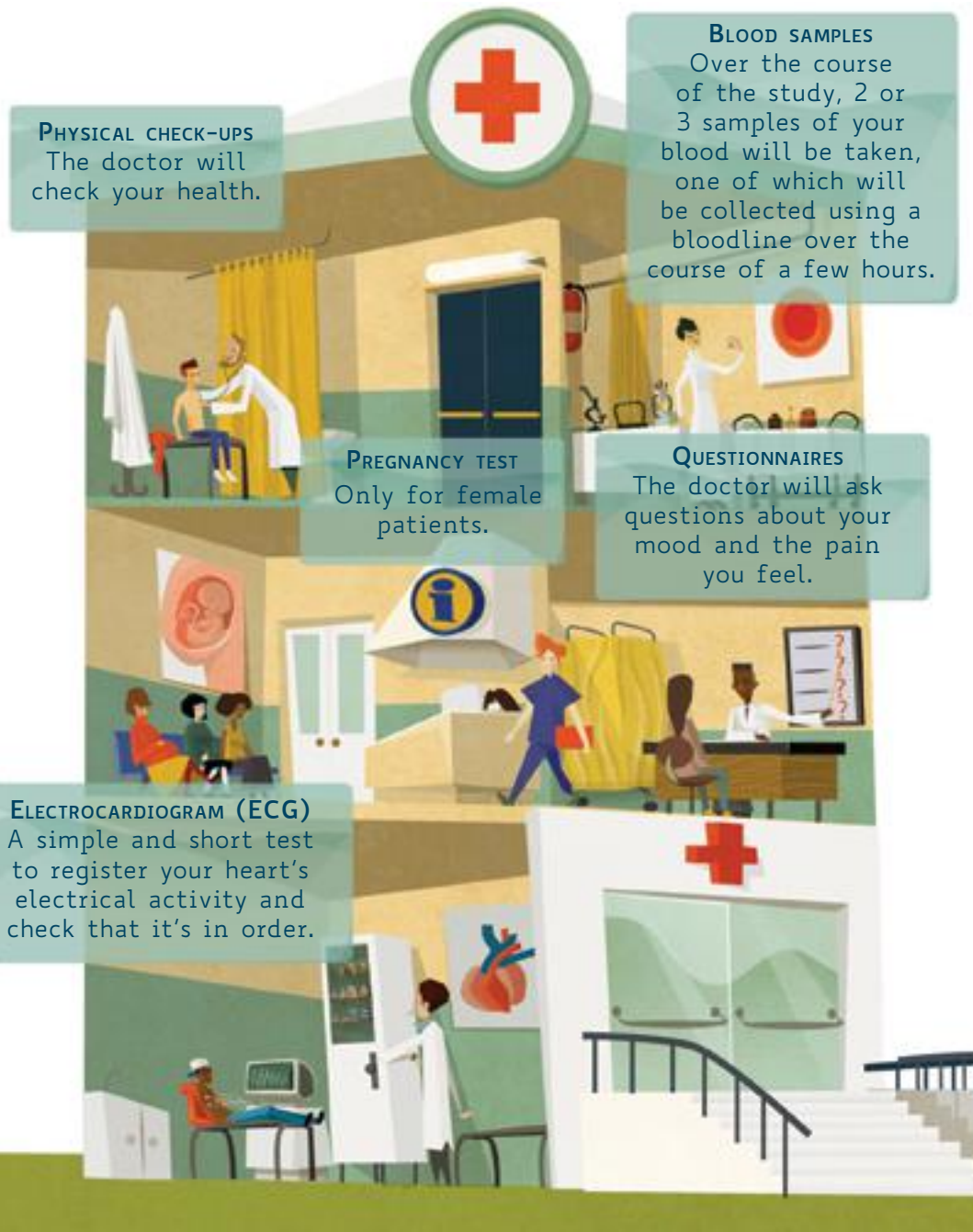
There are 12 planned visits in total, but your doctor may choose to see you for a few extra visits.

At one of the blood tests, 2 or 3 samples of your blood will be taken, spread over a few hours using a bloodline.

If you feel no reduction in pain while taking the new drugs, **alert your doctor.**
He/she will help you by changing your treatment.

On the GABA journey. What will happen during the twelve visits of the GABA-1 study?

What are the tests in the GABA-1 study?



Benefits

You may feel **less pain** than before or **no pain at all**.

You may have a **better quality of life**, and resume your old activities.

You may have **fewer side effects** with the medicine you're taking.

You will help test Gabapentin and possibly make it available to treat **other young patients like you**.

Risks

The GABA-1 study is not dangerous or harmful. You will be closely monitored by your doctor. Most of your duties will involve taking your medication, attending 12 visits, and taking a few tests.

Among the disadvantages, you may find:

- For the first 3 days of the study, you won't be able to take any of your current **analgesics**. However, you will be able to take **paracetamol or ibuprofen** as recommended by your doctor.

- It may take **a couple of weeks** before the new analgesic becomes effective.

- We do not know if these drugs can be **dangerous** for a foetus, so **pregnancy must be avoided**. Your doctor can tell you more about this.

- The drugs may not work properly or have **undesirable side effects**. Generally, higher dosages can cause worse side effects. **Honesty is crucial** when reporting your pain to your doctor and letting him/her know when it is bearable and when it is not.

Side effects

Every human body is **slightly different**. This is why the medicines studied in GABA-1 may have undesirable side effects on you.

These side effects are **known and reversible**. Some people have them, some don't.

They include:

Dizziness

Constipation

Dry mouth

Nausea

Sleepiness

Restlessness

Mood altered

Anger

Depression

Self-harming

Most of these are not dangerous. However, if you ever experience any of these, **alert your doctor immediately** and he/she will be able to help you.

If you ever experience sad thoughts, or are considering harming yourself, remember that **it might be an effect of the drug.** Reaching out to your **parents and your doctor is very important** and can provide a huge relief. Also, your doctor will be able to help you by lowering your dosage.

Pregnancy

We do not yet know whether the drugs in this study are **dangerous for a foetus** and might cause abnormalities and birth defects. So it is **extremely important to avoid pregnancy**. You can discuss this with your doctor who will be able to advise you about using **contraceptives**.

If you do become **pregnant, or suspect that you are,** alert your **doctor** immediately.

Frequently Asked Questions

- Is the GABA-1 study compulsory?

No. You have **total freedom** to decide whether or not to take part.

- Is the GABA-1 study safe?

Yes. Each patient will be in close contact with his/her doctor, and his/her health will **be monitored constantly.**

- Can I leave the GABA-1 study once I've started it?

You can leave the study whenever you like. If you don't feel like taking part any longer, tell your doctor. He/she will slowly decrease your medicine and then you will be able to **leave** the GABA-1 study. After this, he/she will continue to treat you with other medications.

- What happens if I miss a dose of syrup or drops or both?

Make sure you take all the doses on schedule. However, if you do miss one, **follow the instructions provided in the diary.**

- What will happen if I get any undesirable side effects?

Alert your doctor immediately. Undesirable side effects are generally not dangerous and go away over time. Your doctor will decide if it's best for you to continue taking part in the study, or to return to your old treatment.

- What happens if I have a lot of pain?

Alert your doctor. He/she will adjust your treatment to help you feel better.

- Beyond my family and my doctor, who will know if I take part in the study?

Nobody. All your details are confidential and won't be given to anybody. You can decide whether to tell your friends or not.

Protection of privacy and personal data

The personal data of study participants will be treated with the strictest confidentiality and will not be disclosed to anyone outside of the doctor and close family members.

By law (European Directive 1995/46/EC on data confidentiality and local applicable laws), all personnel involved in the study have an obligation to use all the means at their disposal to ensure that any information about you and your condition is kept confidential and that nobody can trace you through the information that is collected about you, except your doctor and the people entrusted to take care of you.

The data will be used anonymously to inform the Ethics Committees of each country involved and the national and European health authorities.

You are entitled to know the results of the study, both general ones and those that directly concern you.

Once the study is completed, the results will be made available to the public, published in a medical journal or presented at a scientific conference.

In any case, any information will be disclosed anonymously and no participants in the study will be identifiable.

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COORDINATOR
Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF)

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

SPONSOR
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.

The **Patient Advisory Board,** established in the framework of GAPP Project and coordinated by Rebecca Lundin (PENTA Foundation), has contributed to the **scientific contents.**

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