WIRB 20081164
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The HARMONY Study

Why is sodium important?

Sodium (salt) is an element of the blood that helps keep a level of stability in the body (in other words a normal, healthy working level). Many diseases or conditions may develop when the body is not balanced properly.

Hyponatremia is a result of the body having too little sodium in the blood. Sodium plays a role in the body of all animals to control blood and bodily fluids, the sending and receiving of nerve signals, heart activity, and metabolic functions (breakdown and use of energy). If the body has too little sodium, it can disturb these functions.

What causes hyponatremia?

Hyponatremia is often caused by medical conditions where bodily fluids/electrolytes are lost (for example, diarrhea, vomiting, or increased urination). Hyponatremia may also occur in conditions where fluids in the body build up too high and sodium in the body is watered down (for example, congestive heart failure, liver disease, or kidney disease). These changes cause the sodium levels in your body to be too low.

Other common causes include consuming excessive water during exercise, hormonal changes, diuretics (water pills to increase urination), polydipsia (extreme thirst), certain medications, dehydration, and diet.

What are the symptoms of hyponatremia?

If you have hyponatremia, you may not be aware of the symptoms caused by low sodium levels. This is because many of the symptoms of hyponatremia can be confused with symptoms of other conditions. The symptoms may be related to increased water in the cells of your brain or other changes to brain cells.

Symptoms may include:

- headache
- irritability
- nausea or vomiting
- mental slowing
- confusion or delirium
- disorientation

In some cases, hyponatremia can result in more serious problems and could become a threat to your life. Problems such as the following have been reported:

- stupor or coma
- convulsions
- respiratory arrest (stop breathing)

Why participate in a clinical research study?

Clinical research studies are designed to test investigational study drugs to make sure they are safe and effective in treating a particular condition and to check for any unwanted side effects. All medications must be tested this way before they can be prescribed by medical professionals. Without clinical research studies, new medications could not be created or tested.

About clinical research studies

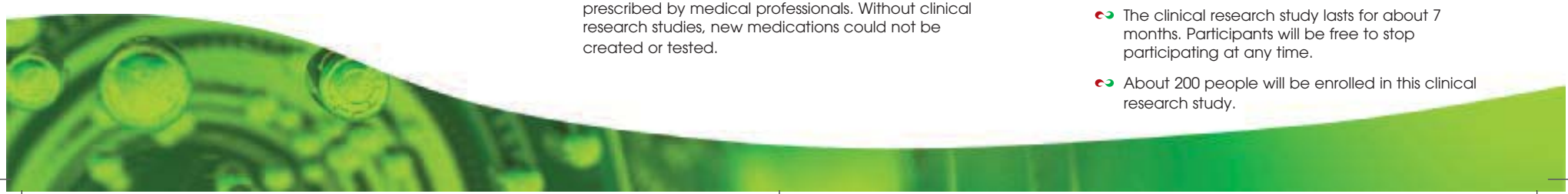
There are multiple organizations that watch over clinical research studies. These include:

- The drug company that is sponsoring the study and its business partners.
- A government agency that sets guidelines for studying investigational drugs.
- An independent ethics committee (EC) or institutional review board (IRB). These organizations are made up of healthcare professionals, researchers, and members of the community. The job of an EC/IRB is to review and approve a clinical research study before it starts. The members of an EC/IRB do not work for study doctors or for the drug company that is sponsoring the clinical research study.

These organizations exist to help protect the rights of all clinical research study participants, while allowing the Sponsor to collect information about the investigational study drug.

About the HARMONY Study

- The HARMONY study is testing an investigational study drug to determine if it can safely and effectively treat people with hyponatremia.
- The investigational study drug is designed to remove extra water while keeping sodium in the body.
- Participants will receive either the investigational study drug being tested or a placebo (inactive drug that looks the same as the active drug).
- The clinical research study lasts for about 7 months. Participants will be free to stop participating at any time.
- About 200 people will be enrolled in this clinical research study.



The HARMONY Study

Do I qualify for participation?

To be qualified to participate in the HARMONY Study, you must:

- Be at least 18 years of age.
- Have been diagnosed with euvolemic hyponatremia (a specific form of hyponatremia caused by normal water levels but low sodium levels).

You must also meet other requirements to participate in the HARMONY Study. To find out if you meet these requirements, you need to talk with a study doctor. The study doctor will ask you further health related questions and may ask your permission to perform some medical tests to check to see if you can participate.

What to expect if you participate

If you agree to participate and you meet the requirements for participation, you will be enrolled into the HARMONY Study. During the clinical research study, you will be asked to:

- Stay at the study site for about 8 hours after your first dose of investigational study drug to be watched over by study staff.
- Take the investigational study drug as prescribed for about 4 months.
- Come to the study site for 14 more study visits, including two follow-up visits, over the next 5 months.

To learn more about the HARMONY Study…

If you or someone you know is interested in learning more about the HARMONY Study, please contact us at the number provided below for more information.

Clinic Name:

Address:

Telephone:

88276 HARMONY Brochure v2.0 US (English) 26.Aug.09

The HARMONY Study

Do you know about hyponatremia?

Hyponatremia is a condition where your body has a low level of sodium (salt) in the blood. If you or a loved one has been told by a doctor that your sodium levels are too low, you may be interested in the HARMONY Study.

The HARMONY Study