Study information and Consent form

Request to participate in a drug study (new way to inject botulinum toxin (Botox®) into the scalp in chronic migraine »Follow the sutures»)

Background and purpose

This is a request to you to participate in a research project that involves testing the drug Botox®, injected in various places on the scalp in chronic migraine. Botox® is already used for this condition, but this study will see how patients respond in a new way to put the injections (above the joint sutures of the skull bones), with almost half the dose and fewer injection. The study is done by personnel at the National Competence Service for Headaches at St. Olav's Hospital and at the Department of neuromedicine and movement science at NTNU, and without support from the pharmaceutical industry. The study is also being done at a headache center in the USA.

What does the study mean for you?

The study lasts a total of approximately 16 weeks and no samples are taken. At the first visit, the doctor will decide if you can participate in the study. Next, you will keep a headache diary for 4 weeks (run-in period) before coming to a new doctor's visit. If the diary confirms that you have chronic migraine, you will receive the injections with Botox®, and question about how painful it was.
Next, you should keep a headache diary for another 12 weeks for you comes to a third and final doctor's visit to complete the study.
During the study, a project nurse will call you 3 times in total to ask how you are doing. All participants in this study receive the same dose of medicine in the same places on the scalp.
If you do not want to participate you will be offered standard treatment for your condition, most often preventive medicine or Botox® given according to standard procedure. You can use acute pain medication and up to one preventive migraine medication while you are in the study.

Possible advantages and disadvantages

By participating, you will receive an accurate record of your headaches and medication use in one four-month period.
Only downside is that there may be little or no effect on the headache, but it can also be that it has good effect.
In general, there are few problems with Botox® given after standard procedure, and we expect even less side effects with the new way since the dose is smaller and you put it in a more.

What happens to the information about you?

The samples taken from you and the information registered about you should only be used as described for the purpose of the study. All information will be processed without name and birth number or others directly recognizable information.
A code links you to your information and tries through a list of names. It will not be possible to identify you in the results of the study when these are published.
The information will be stored for 15 years after the final report for the study is available. Information about patients who withdraw from the study will be stored for the same length of time. It is not possible to delete information even if you withdraw, but new data will not be collected.

Participation is voluntary
Participation is voluntary, and it is possible to withdraw from the study at any time without any consequences for your further treatment. You sign the declaration of consent if you wish to participate.

Contact Information

If you have questions about the study, contact the project manager, professor Lars Jacob Stovner, phone 72 57 50 70, email: lars.stovner@ntnu.no, or study nurse Gøril Bruvik Gravdahl, phone 72 57 51 47, email goril.b.gravdahl@stolav.no.

Detailed explanation of the study

Background
Botulinum toxin A (Botox®) is a muscle-paralyzing poison that is now used in very small doses to treat a number of conditions, including migraines. Today's method for chronic migraine treatment with Botox ° gives few side effects and carries little or no risk, but it involves many syringes (31 to 36) in scalp.
Many patients find it painful, it is expensive and it takes time for the doctor. Animal studies suggest that putting the injections in slightly different places can achieve a better effect with fewer stings, less pain and lower dose
In this study, via examining how patients experience this new way of putting Botox ®, how painful it is, how long it takes, and also see if it can be as effective on the headache as the standard method. All patients in this study will receive the injections same measure, and with Botox ®. There are no examinations beyond the usual clinical examination, and no samples should be taken.

Who can participate?
Patients 18 to 65 years, with chronic migraine for at least half a year, and who have not received Botox or similar preparations previously may participate.

Patients must not have certain rare muscle diseases, severe psychiatric problems, or problematic use of alcohol or drugs. Patients who may have so-called drug overdose headaches in addition must have tried weaning for this.

Study details

If the doctor says you can participate, you must sign a consent form. You will then be asked to complete a headache diary every day for the 16 weeks the study lasts. The project nurse will explain to you how this is done. After 4 weeks you will come to a new visit. If the headache diary confirms that you have chronic migraine, you will receive Botox ° injections (18 points in the head, a total of 90 Units Botox °). Immediately after the injections, you will be asked to grade the pain of the procedure itself, and you will be asked to keep a diary again in
another 12 weeks. When this is done, you will have a final appointment with the doctor. The project nurse will call you one week after you were included in the forums to hear how you are keeping a diary, and 1-2 and 8-9 weeks after the treatment with Botox ° to hear about any side effects or other health problems. We are particularly interested in whether you will have a temporary paralysis of the forehead muscles, so we will ask you about the ability to
wrinkle pans.
A total of 40 patients will participate in the study, 20 in Norway and 20 in the USA. This is a so-called pilot study, i.e. an preparatory study to gather experience for a possible larger study with several hundred patients.

What happens if you do not want to participate or withdraw from the study?
Then you will get the best standard treatment, based on what diagnosis you have and how much bothered you are. It can be revision of acute pain medication or preventative medication or use of Botox® as we usually inject.

Privacy
Information that is registered about you is age, gender and education, as well as other diseases and previous and current use of medication, in addition to information about your headache. It will not be possible to identify each individual patient when the results of the study are to be published.
Representatives from the sponsor, the Norwegian Medicines Agency and control authorities at home and abroad can be given study information and given access to relevant parts of your medical record. The purpose is to check that the study information corresponds with the corresponding information in your journal. Everyone who gets access to information about you has a duty of confidentiality. The study will be conducted in collaboration with a center in the United States. A researcher from there will be able to access completely anonymized data when we analyze and write about the results.

Right of access and storage of material
If you agree to participate in the study, you have the right to access the information that is registered about you. You also have the right to have any errors corrected in the information we have registered. If you withdraw from the study, no more information or material will be collected. Information already collected from you will not be deleted.

Financing
The study is funded by the National Competence Service for Headaches at St. Olav's Hospital in Trondheim. The sponsor of the study is the head of the Department of Neurology and Clinical Neurophysiology at this hospital, chief physician, Ph.D. Geir Bråthen. The role of the sponsor is to ensure that national and international guidelines for such studies are complied with. Neither the sponsor nor the testers will have any financial gain from the study, and there are no conflicts of interest associated with it.

Insurance
You are insured in accordance with the Product Liability Act in the Medicines Insurance (the «Medicines Liability Insurance»).

Information about study results
You will have the right to know the result of the study.

Consent to participate in the study
I am willing to participate in the study

(Signed by project participant, date)

Confirmation that information has been provided to the study participant

I confirm that I have provided information about the study

(Signed, role in the study, date)