[ImpresU, 16.10.19, version 3]

Request to participate in drug trial

Version 3

ImpresU - can Methenamine reduce episodes of urinary tract infections (UTI) in women over 70 with recurrent UTI?

This is a request for you to participate in a research project testing the drug methenamine hippurate. Methenamine disinfects the urinary tract and is not regarded as an antibiotic. Methenamine is the most commonly used drug for preventive treatment of urinary tract infections in Norway. The aim of the study is to determine whether methenamine has a preventive effect and leads to fewer infections in women over the age of 70 with frequent urinary tract infections. Your General practitioner (GP) has, through a computer program searching his/her medical records, found that you are a patient frequently suffering from urinary tract infections. Based on these finding, he/she has contacted you to require your participation in a study testing a preventive drug for urinary tract infections.

The study is conducted by the (Insert national research group/university), and the sponsor of the study, The University of Oslo.

What does the project entail?

In this study, we wish to investigate whether methenamine has a preventive effect on urinary tract infections in women over the age of 70. In order to do so, we will be testing methenamine against placebo over a period of six months. In the Norwegian part of the study, 100 patients will be participating. One half of the patients will get methenamine, while the other half will get placebo tablets. The study is blinded, which means that neither your doctor nor the research team will know whether you get methenamine or a placebo. This information is sealed and only to be revealed if a situation where it is important to know whether you are getting the active drug or not occurs. The medicine is free of charge, and you will be given medication for six months of treatment. After the treatment period, we wish to continue the follow up for an additional six months in order to investigate whether methenamine has a prolonged preventive effect even after the treatment is completed.

At the first meeting, a representative from the research team will give you information on the study, and you will get the opportunity to ask any questions you might have. If you wish to participate, we will get your GP to help us determine whether you are an eligible

candidate for the study. By signing this declaration, you consent for the research team getting access to relevant information in your medical records through your GP. We will also be asking you for a urine sample during this meeting.

If you are getting symptoms of a urinary tract infection within the study period, we ask you to contact your GP in the normal manner for an evaluation of treatment. At this consultation, a urinary sample will be taken. We also ask you to contact the research team on the same day using the listed number. After this, our study nurse will contact you once a week until your infection has cleared. During these calls we will register symptoms and the degree of symptoms, what kind of treatment you receive and the duration of the treatment. Any side effects or complications due to the study medicine will also be recorded. Our study nurse will call you once a month throughout the treatment period the first six months of the study to check up on you and to see how you are doing.

If you get a urinary tract infection and your doctor is not available, we ask you to contact other health care institutions to get an evaluation of treatment and thereafter call the research team on the listed number. By signing this declaration, you give your consent for the research team to collect relevant data from your medical records at the health care institution you received your treatment if necessary.

POSSIBLE ADVANTAGES AND DISADVANTAGES AND SERIOUS SIDE EFFECTS

Methenamine has been used for nearly 50 years without a documented effect. It is important to clarify whether methenamine actually can reduce the number of episodes in women with frequent urinary tract infections. If so, more patients can benefit from an effective preventive treatment. This will lead to a reduction in antibiotic prescriptions for urinary tract infections, and contribute to reduce the development of antibiotic resistance in the future, as well as saving patients from the unnecessary side effects of antibiotics.

If methenamine does not show a preventive effect on frequent urinary tract infections, this will cause many women not to be prescribed unnecessary medicine.

Since methenamine has been used on a large scale in this country, the drug has a well-documented safety profile with few and mild side effects. We do not know of any serious side effects linked to the use of methenamine. The most common side effects that can occur are all less common (more than 1 of 1000, less than 1 of 100) and include stomach disorders such as nausea/vomiting, stomach irritation, upset stomach and rash/itching and irritation of the bladder. A rare side effect (more than 1 of 10 000, less than 1 of 1000) is microscopic (not visible) blood in the urine.

The treatment of every episode of a urinary tract infection is determined by your doctor in the normal manner. Participation in the study will therefore not result in any other treatment for your urinary tract infection than you would otherwise have.

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VOLUNTARY PARTICIPATION AND POSSIBILITY TO WITHDRAW CONSENT

It is voluntary to participate in the project. If you wish to participate, you have to sign the consent form on the last page. You can, whenever you like and without stating a reason, withdraw your consent without any consequences for further treatment.

If you consent to participate in the study, you have the right to gain access to the information registered on you and have the information corrected should there be any mistakes in your information. You also have the right to gain insight into the security measures taken in the processing of your data. If you wish to withdraw from the study, there will not be registered any more information on you, but data already collected will not be deleted.

If you wish to withdraw your consent or have questions about the project, you can contact (Insert contact information for Principal Investigator).

WHAT HAPPENDS TO THE COLLECTED DATA ON YOU?

The tests will be done in the same manner as any other tests taken in your GP's office, and are requisitioned by your doctor. We will not collect biological material, and are only interested in the results from the tests your doctor required.

The results we will require are from urinary dipsticks, ph and culture. If there is growth of bacteria in your urine culture, the bacteria will be investigated further, but your urine sample will be destroyed in the usual manner.

The tests taken, and the information registered on you, are only to be used as described in the purpose of the project.

All the data on you is processed without a name or a national identification number, or any other recognizable information. A code will link you to your information through a list of names.

It is only (insert all persons that have access to the national list) who have access to this list. The list will be securely stored at the research center.

This study is a cooperation project between Norway, Sweden, the Netherlands and Poland. The study will take place simultaneously in the four participating countries. After coding, the data on you will be gathered in a database in the Netherlands where final analyzes will take place. The data from all the participating countries will be analyzed collectively and are later to be published in international journals.

By participating in the project, you consent to the information being transferred to other countries as a part of a research and publishing collaboration. The project leader will make sure that your data is taken care of in a safely manner.

The code that links you to your personal identifiable information is not transferred.

Your collected data is to be deleted 15 years after the project has ended.

It will not be possible to identify you in the results of the published study.

APPROVAL

(Insert name of Competent Authority) has evaluated the project and given their approval (Insert study reference number).

According to the new personal data act, the data controller institution, (Insert name of university and name of Principal Investigator), have a personal responsibility to ensure that the handling of your information has a legal basis. This project has the legal basis in the EUs General Data Protection Regulation, article 5, article 6 1a and article 9 2a, and your consent.

You have the right to complain about the processing of your information to the Data Protection Authority.

CONTACT INFORMATION

If you have any questions about this project, please contact (Insert name and contact information for coordination researcher).

You can contact the Data Protection Official at the institution if you have questions about the processing of your personal data in the project. At the (insert university), questions about data protection are addressed to (insert contact information).

WHAT INFORMATION ABOUT YOU WILL BE REGISTERED?

- Relevant past medical history to determine if you are eligible to participate in the study.
- Year of birth and residency
- Certain other health information important for the evaluation of the results of the study. We will be collecting this information from your GP, your medical records and from you directly.
- During the first meeting, we will take a urine sample and register the results of this test.
- With every episode of a urinary tract infection, we will register symptoms and the degree of the symptoms, what treatment you receive and the duration of the treatment. The results of the urine test taken by your doctor with every episode will also be registered. In every case of a urinary tract infection, we will follow up to register the course of the infection until the infection has cleared. Any side effects or complications due to the study medicine will also be recorded. Our study nurse will call you once a month throughout the study to check up on you and to see how you are doing.

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- If you receive treatment for a urinary tract infection from other health professionals than your GP, it may be necessary to collect information from their medical records as well in order to obtain the information listed above.

- Representatives from The University of Oslo (the sponsor of the study), The Norwegian Medicines Agency and control authorities, both domestic and abroad, can gain access to study information from relevant parts of your medical record. The purpose of this is to ensure that the registered study information match the information in your medical record. Everyone with access to your medical record have a duty of confidentiality.

FINANCE

The study is funded by (Insert source of funding); the sponsor of the study is The University of Oslo.

INSURANCE

You are insured in accordance to the product liability law in (Insert national insurance company).

INFORMATION ABOUT THE OUTCOME OF THE STUDY

The participants in the study have the right to get information about the outcome of the study if desirable.

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I CONSENT TO PARTICIPATE IN THE STUDY AND THAT MY PERSONAL INFORMATION CAN BE USED AS DESCRIBED.

(Signature of participant, date)

CONFIRMATION OF GIVEN INFORMATION

I confirm to have given information about the project

(Signature, role in the project, date)

*Note: The model consent form will be adapted according to rules and regulations from the competent authorities in each participating country.