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The FAST- Study: The Follow-up After Shorter Tapes Study Effectiveness and Safety of Shorter Trans-obturator Tapes: A Prospective Observational Study From the Norwegian Female Incontinence Registry

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The FAST study

The **F**ollow-Up **A**fter **S**horter **T**apes **S**tudy

WOULD YOU LIKE TO PARTICIPATE IN THE RESEARCH PROJECT:

LONG-TERM FOLLOW-UP AFTER AN OPERATION FOR URINARY INCONTINENCE AT AHUS?

PURPOSE OF THE PROJECT AND WHY YOU ARE ASKED TO PARTICIPATE

Would you like to participate in a research project aimed at investigating long-term results after operations for urinary incontinence at Akershus universitetssykehus (AHUS)? The purpose of the project is to evaluate if operated women still have a good result and are still continent many years after surgery and if anyone has had surgery-related complications.

During urinary incontinence surgery a synthetic band is often placed under the urethra. At AHUS two types of slings with shorter length than conventional slings have been used since 2009, called Ajust and Abbrevo. Studies have shown that these shorter slings work well the first two postoperative years, but we know little about the long-term results. Therefore, we are now contacting all women who have been operated at AHUS with these slings in the period 2009-2020 to investigate long-term results. Those who agree to participate will be asked to complete an electronic questionnaire. Some women will also be offered a clinical examination by a nurse and a gynecologist (including ultrasound) to see if the sling is placed correctly and to check if there are any sling-related complications.

All women operated for urinary incontinence in Norway are registered in a national quality registry called the Norwegian female incontinence registry (NFIR). You are contacted since you, according to NFIR, have been operated with one of the shorter slings at AHUS in the period 2009-2020.

WHAT DOES THE PROJECT ENTAIL?

1. After you have read the complete information, you may participate in the study by answering Yes to participate online. By answering Yes you automatically consent to study participation. In addition, you also give us permission to link your information collected in this project to previously stored information collected form you before surgery and at the 6 to 12 month's check-up after the operation (if you attended such a follow-up). If you have had later operations for urinary incontinence or have later been treated for surgery-related complications at other hospitals than AHUS, by answering Yes to participate you also give us your consent to retrieve this information.

After answering Yes to participate, we ask you to provide general health information as well as to answer questions on urinary leakage and complications you might have experienced after surgery, including pain that may affect some women after the operation. It is important that all questions are answered. The questionnaire takes 20 minutes to complete.

If you have questions about the project or want to know more before you log in, please contact the project manager Kjersti Rimstad, on telephone number 67960000 or email: kjersti.rimstad@med.uio.no

If you have questions about data protection in the project, you may contact the Data Protection

Officer at AHUS: forskning.personvern@ahus.no

2. If you do not want to participate in the study electronically, but want to participate by a paper questionnaire sent by mail, you can answer Yes to participating by mail. You will then receive a paper questionnaire sent by mail. You will have to fill in the paper questionnaire and thereafter return the questionnaire in the attached fully franked envelope.
If you have not responded at all, or you have consented to participate and we do not receive your response within 4 weeks, we will contact you by telephone in case you want to participate, but have forgotten it. You then choose whether you want to participate in the study and answer the questions by telephone.
If you choose to answer via telephone and you have not agreed to participate in the boxes belove, you will receive a consent form by mail that you must sign and return in the attached fully franked envelope so that we can use your information in the study.

3. In the questionnaire, some of you will be asked if you are willing to attend a physical follow-up. This physical follow-up involves a nurse examining your urine flow. A gynecologist will also perform a gynecological examination including ultrasound examination of the synthetic sling.

If you wish to participate, but cannot come for a physical follow-up, your participation and answers to the questionnaire will still contribute important information to our study and thereby also important knowledge to women who are considering urinary incontinence operation with these methods in the future.

POSSIBLE ADVANTAGES AND DISADVANTAGES

As a participant in this project, you will contribute to highlight how efficient this operation is for women and if there are long-term concerns that we previously have not been aware of. The knowledge we seek from this project will improve our ability to help other women with urinary incontinence. If the long-term follow-up shows that you have bothersome symptoms after the operation, you will be offered further follow-up to examine and treat the problem.

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW CONSENT

Participation in the project is voluntary. You can withdraw your consent at any time without stating a reason. There will be no negative consequences for you or your treatment if you do not want to participate or if you choose to withdraw at a later stage. If you withdraw your consent, your health data will not be used in any further research. You may request access to your data, which will be provided within 30 days. You can also request for your project data to be deleted and for the destruction of your ultrasound pictures.
The right to have your data and material destroyed, deleted or returned does not apply if the material or data are already published in anonymous form. Access may also be restricted if the data have been included in analyses already performed, or if the material has been processed.

If you want to withdraw at a later stage or have questions about the project, you can contact the project manager (see the contact details above).

WHAT HAPPENS TO YOUR DATA?

Your registered data will only be used as described under the purpose of the project, and is planned for use until the project ends, at the latest in 2030. Use and storage time can only be extended after approval from the Regional Committee for Medical and Health Research Ethics and the Data

Protection Officer at AHUS. All data will be made anonymous 5 Years after study completion. You have the right to access the information that is registered about you and to have any errors corrected. You also have the right to access information about the data security measures that apply to the processing of the data. You can present a complaint about the processing of your data to the Norwegian Data Protection Authority and AHUS`s Data Protection Officer (please see contact data at the last page).

All data will be processed without names and personal identification numbers or other directly identifiable information (= coded data). A code links to your data through a list of names. Only project manager Kjersti Rimstad has access to this list of names.

Publication of results is an essential part of the research process. Data in the published research will be anonymous to preserve the privacy of individual participants.

After the research project is completed, your data will be stored for 5 years for control purposes before they either will be erased or made fully anonymous.

WHAT HAPPENS WITH THE ULTRASOUND FOOTAGE THAT ARE TAKEN OF YOU?

If you have had an Ultrasound examination, the images will be stored in a secure research database at AHUS as part of the project.

After the research project is completed, your collected data will be stored for ten years for control purposes. After this, they will be deleted or anonymized.

APPROVALS

The Regional Committee for Medical and Health Research Ethics has considered the research ethics in the project and given its approval (Case number 662038). The study is voluntary and consentbased. The registered consent must be used. The study has a legal basis in the general privacy regulation article 6 no. 1 letter e) and article 9 no. 2 letter j).

AHUS and the project manager Kjersti Rimstad are responsible for privacy and data protection in this project.

CONTACT DETAILS

If you have questions about the project, or if you experience any adverse events or side effects, or want to withdraw your participation, you can contact Kjersti Rimstad, telephone number: 67960000 or email: Kjersti Rimstad, 67960000, e-post: kjersti.rimstad@med.uio.no

If you have questions about data protection in the project, you can contact the Data Protection Officer at AHUS: forskning.personvern@ahus.no