Participant information for participation in a scientific experiment

Randomized comparison of Evolut FX versus Sapien 3 Ultra Resilia
The Compare-TAVI 2 trial

You are having a new heart valve inserted through the femoral artery in the groin. Running alongside this treatment, we are also performing a research study, and we would like to ask you to participate in this research.

Before you decide whether you want to participate in the research, you must fully understand what the research is about, and why we are conducting this clinical research. We would therefore ask you to read this participant information carefully.

You will have a meeting with a doctor who have specialist knowledge in heart valve disease, where this participant information will be elaborated, and where you can ask any questions, you might have regarding the trial. If you wish, a family member, friend or acquaintance can join the conversation.

If you decide to participate in the trial, we will ask you to sign a consent form. Remember that you are entitled to a period of reflection before you decide whether you want to sign the declaration of consent.

Participation in the trial is voluntary. You may at any time and without giving a reason withdraw your consent, without it having any impact on your future treatment.

Purpose of the research

There are several different types of heart valves that can be inserted through the artery in the groin. They are called "Stent valves". They are all approved for use in Europe. At a multidisciplinary heart valve conference, we have reviewed your cardiac CT scan and other investigations. During this assessment we have concluded that either one of two different valves we use routinely can be used to treat your narrowed heart valve. The names of the valves are: Medtronic Evolut FX and Edwards Sapien 3 Ultra Resilia.

With the current study, we want to compare the long-term durability of the two valves. If you choose to join the study, the choice of stent-valve will be made by drawing lots. The purpose of the examination itself is to follow all patients to monitor patient survival, function of the stent valve, and whether leaks or constrictions of the valves occur, or whether stroke develops afterwards, or complications arise. We thus want to see if the two valves perform equal during follow-up.

Who can be included in the study

Patients who need to have a stent-valve operation via the groin.

How many patients should be included in the study

1346 patients will be included internationally in the comparison of the above two valves.

Plan for the research

If you participate in this research study, you will be treated with one of the two stent valves mentioned above. The treatment itself takes place in accordance with the department's current routines, and the current study has no influence on the treatment in general. During the study we do clinical follow-up on patient condition after 30 days, 1 year, 3 years, 5 years and 10 years to find out if the patients who have joined the study are alive, have had a stroke, whether their heart valve is functioning well, and whether they have had a pacemaker implanted or any complications. In addition, we will assess if the valve is malfunctioning using ultrasound scans of the heart or CT scans over this 10 year follow-up period.

Control and follow-up examinations:

The current recommendations for follow-up after stent valve treatment will be followed (1 month, 1 year, 3 years and 5 years). Were possible we will carry out this follow-up at the university department rather than at the local hospital. In addition, we will offer an extra follow-up after 10 years.

Usefulness of the research

There are no definite benefits associated with participating in the study. However, the study may benefit future patients if it turns out that one of the two stent valves being compared is significantly better in terms of the research results.

Side effects, risks, complications and disadvantages

There are no additional risks associated with the study. Prior to participating in the study, physicians with extensive experience in the treatment have assessed that the two above-mentioned valves are equivalent for the treatment of your narrowed heart valve. All other treatment takes place according to the department's routine.

Disclosure of information from your journal:

In connection with the study, data on previous illness (hypertension, diabetes, stroke, blood clot in the heart, heart failure), age, sex, the results of previous coronary artery examination, details of the operation, and the results of ultrasound scan of the new heart valve will be recorded together with follow-up clinical checks, as well as any cardiac CT scans of the heart. This information is used only in the study context and is anonymized at the end of the study. This data will primarily be obtained from your clinical journal and follow-up appointments, and from national registries. The purpose is to use the information in anonymous form in connection with the preparation of a scientific article. The ultrasound scans and cardiac CT scans will be anonymized and transferred for analysis by experts at Aarhus University Hospital (Denmark) to prepare scientific articles. Cardiac CT, ultrasound scans and images from the procedures will be evaluated by experts in so-called core laboratories. Data can be used in collaborative research, i.e. combined with other similar studies, but in anonymous form.

Duty of confidentiality

Your journal is treated confidentially. Data will be collected electronically via a system designed for the purpose and with necessary safety. Necessary information about your health, your other purely private matters and other confidential information will be passed on and processed as part of control of the research project, including quality control and monitoring, which the sponsor or any monitor is obliged to perform. Data will be treated anonymously for scientific purposes.

Who is responsible for the study:

The study is investigator-initiated, i.e. by physicians performing heart-valve implantations. Sponsor is Aarhus University hospital, Denmark. Heart centers all over Europe are eligible for participation in the study. In each county, a national investigator is responsible for ethical approval.

Information on financial matters

The current comparison between Evolut FX and Sapien 3 Ultra resilia will receive funding from Medtronic A/S, up to a maximum of 3490 Euro if a patient is followed for 10-years with both Echo and clinical follow-up. The Danish Heart Foundation has supported the Compare TAVI organization with a grant of 275,000 euro. The money is used to cover salary for research staff working with the study. Project managers will not receive any personnel honorarium but can be bought free from clinical work at their institution to prioritize the current research.

Fees for subjects

No fee is paid to patients who participate in the study. However, we travel expenses can be covered when you go for follow-up.

Treatment of persons not participating in the trial:

Failure to participate in the trial will not affect your treatment. You will only have one of the above heart valves implanted, but it will not be selected by drawing lots.

Interruption of the trial as a whole:

The research study is interrupted if: 1) information emerges which should document that one valve is worse than the other, 2) it is not possible to raise funding for the conduct of the study.

Exclusion from further participation in the trial:

If a patient regrets participation, they can withdraw their consent at any time.

Access to trial results

The study will be published in an international medical journal by the doctors who have planned the study.

We hope that with this information you have gained sufficient insight into what it means to participate in the trial and that you feel informed enough to make the decision about your possible participation. We also ask you to read the attached material "The subject's rights in a health science research project".

If you want to know more about the research, you are very welcome to contact the undersigned.

Sincerely

Local investigator contact details here

The rights of a trial subject in a biomedical research project

As a participant in a biomedical research project you should know that:

- your participation in the research project is completely voluntary and can only take place after you have received both written and oral information about the research project and signed the consent form;
- you may at any time orally, in writing or by any other clear notification withdraw your consent to participation and withdraw from the research project. If you withdraw your consent, this will not affect your right to any current or future treatment or any other right you may have;
- you are entitled to bring a member of your family, a friend or an acquaintance with you to the informative interview;
- you are entitled to time to think it through before you sign the consent form;
- strict confidentiality is observed with regard to information about your health, other purely private matters and other confidential information about you disclosed in connection with the research project;
- information about you, including information about tissue and blood samples from you, will be processed according to the provisions specified in the General Data Protection Regulation (GDPR), Danish Health Care Act and the Danish Data Protecting Act . The data controller must inform you about your rights under the data protection rules;
- you will be able to get access to research protocols according to the provisions of the Danish Open Administration Act. This means that you can gain access to all documents concerning the organization of the project apart from the parts containing business secrets or confidential information about others.
- you have the right to complain and compensation can be paid pursuant to the Act on the Right to Complain and Receive Compensation within the Health Service. You can contact Patienterstatningen if any damage occurs. Read more information at www.patienterstatningen.dk .

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(S1) Informed consent to participate in a health science research project.

(Patient copy)

The title of the research project:
Randomised comparison of Evolut FX versus Sapien Resilia = Compare TAVI 2 trial

Statement from the subject :

I have received written and oral information and I know enough about the purpose, method, advantages and disadvantages of saying yes to participating.

I know that participation is voluntary and that I can always withdraw my consent without losing my current or future rights to treatment.

I give consent to participate in the research project, and have received a copy of this consent sheet as well as a copy of the written information about the project for my own use.

Name of subject: _____

Date: _____ Signature: _____

Do you want to be informed about the result of the research project and any consequences for you ?:
Yes _____ (set x) No _____ (set x)

Statement from the person providing the information:
I declare that the subject has received oral and written information about the experiment.

In my opinion, sufficient information has been provided to enable a decision to be taken on participation in the trial.

The name of the person who provided the information:

_____

Date: _____ Signature:

(S1) Informed consent to participate in a health science research project.

(Project copy)

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