Research patients information and informed consent

Research subject: Marched Pair Study Conventional Doxorubicin(DOX) Versus Pegylated Liposomal Doxorubicin(PLD) Neoadjuvant Chemotherapy

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Subject name: **research cente:** **doctor:**

We invite you to participate in a clinical study ,before you decide whether to join in ,you need to know why to carry out the study,how to use you information,which content the research includes,what the possible benefits, risks or discomfort are.Please read the following information seriously, if you hope,you can discuss with your doctor.

The background and content of the research

Chemotherapy is the treatment that most breast cancer patients need to undergo.Anthracyclines is currently irreplaceable type of drugs because of its significant effect.But the most serious side effect of anthracycline is heart damage,which is often irreversible and clinically important.

A new generation of anthracyclines,PLD,has been shown to have low cardiac toxicity in elderly people with high risk of heart disease and advanced breast cancer because of lipid package.This study further compares the effects and side effects of PLD and traditional anthracyclines in the neoadjuvant chemotherapy for breast cancer,especially the drugs'cardiac toxicity.

Your possible risks:

Participating in this study does not change your doctor's treatment and medication for you,there is no need to increase the cost of examination and medicaton compared to patients who refuse to participate in this study,so it won't bring your any damage or loss beyong the therapy.Your information is only uesd to analyze the efficacy and side effects of the drug and is limited to the use of the team members.Participants don't increase their risk compared to rejecting participants.

Your possible benifits:

For this study,you will be reimbursed by the project team for six months and a year for cardiac examination.And the information we get from this study will help us better treat more breast cancer patients.

Project process:

When you agree and take part in this research project,first of all,you will be asked by your doctor about the relevant personal information,medical history,etc.The second step is to review and record the pathology,examination and inspection informtion of the breast cancer by your doctor.Step3:after each admission to the hospital for neodjuvant chemotherapy,your doctor asks and records the information required for the study.Step4:after treatment in this research center,the patients according to the surgery date calculation,half a year,a year,reexaminate electrocardiogram and echocardiography in outpatient service,tell the follow-up person results,and give the receipts to the project director.This expenditure will be reimbursed after the project manager declared it.Finally,the data collation analysis is carried out by the relevant organizations of the project.

Stop the experiment:

1 You are enitled to withdraw from the study at any time during the process,which will not affect the standard treatment you have received.
2 You don’t follow your doctor’s instructions in the study.
3 You are selected wrongly for this study before randomization.

What do you need to do?

1 You must tell your doctor about any changes or symptoms of your health,whether you think they are related to your treatment or not.
2 You must attend all the planning visits.
3 If you have any questions,please feel free to contact your doctor.
4 Follow the instructions of the staff.

What are the costs after participating?

The research unit will not pay you the cost of labor or other damages or loss,or medical expenses covered bymedical or hospital insurance,or medical expenses covered by a third party or government projrct.Apart from th providing the inspection fee of electrocardiogram and echocardiography in outpatient service of research center in three months,six months and one year after operation,we will not be able to provide other expenses.

How to use your information.

After signing this agreement,you agree to study the personal data collected by the doctor and his staff(research data).Please note that the findings may be published in the medical literature,but your identity will not be identified.You have the right to ask for your research data.You also have the right to ask for corrections to inaccurate data.If you have such a request,please contact your research doctor.If you withdraw your consent,the doctor will no longer use the data or provide it to others.However,the research unit can use the data you provided before you withdraw your consent.
If I need more information and help,who should I contact?
Doctor: The phone number：
Address：
If you have any questions about your rights as a rsearch patient,please cantact:

Informed consent statement

Patients with signature: Date of signature:
If the patient is unable to sign the signature,It is required by the law to be signed by the representative and marked with the patient’s relationship.
Representative’s signature acceptedby the law:
Date of signature: