3-PILLARS STUDY

SUMMARY PATIENT

INFORMATION SHEET

We would like to invite you to take part in the 3-Pillars study. Before you decide, it is important that you understand why the research is being done and what it will involve for you. Please take time to read the following information carefully. If this summary interests you and you think that you might like to take part please read the detailed Patient Information Sheet provided by the research staff.

Please ask if there is anything that is not clear or if you would like more information. If you decide you would like to take part in this study, your participation will be voluntary and you will be free to withdraw at any time.

PURPOSE OF THIS STUDY

The purpose of this study is to look at a combination of breast cancer treatments given to shrink the tumour before surgery to remove it. Treatment given before surgery is called neoadjuvant therapy and this can be either hormone therapy or chemotherapy. If your breast cancer has a significant number of receptors for either oestrogen or progesterone, it is considered oestrogen-receptor positive (ER+) or progesterone-receptor positive (PgR+).

It is known that ER+ breast cancers generally respond less well to chemotherapy and that not all such cancers need chemotherapy. Given all the possible side effects of chemotherapy it is important we try to avoid treating women in whom it will provide little or no benefit. ER+ breast cancers are routinely treated with hormone therapy that block the oestrogen receptor. It is known that such hormone therapy is more effective when combined with another drug which blocks a molecule called CDK4/6.

Half of all ER+ breast cancers also express a receptor called human epidermal growth factor receptor 2 (HER2) and effective treatments are available for breast cancers which express this receptor. Such treatments are key for HER2-positive (HER2+) breast cancer and are routinely used. Research has shown that the combination of HER2 therapy with hormone therapy is more active than hormone therapy alone.

This study will treat patients with early breast cancer that is ER+, PgR+ and HER2+ and will consist of a combination of treatments: letrozole to block oestrogen receptor, trastuzumab and tucatinib to block HER2 and palbociclib to block CD4/6.

All patients entered will be followed up and data collected on how effective the treatment received at shrinking the breast cancer recorded.

STUDY MEDICATION

All study drugs are licensed anticancer drugs currently used to treat a variety of cancers, but may not be licensed to treat early breast cancer.

- Palbociclib is a tablet which is taken orally once a day for 21 days with one week off.
- Tucatinib is a tablet which is taken orally twice a day.
- Letrozole is a tablet that is taken orally once a day.
- Trastuzumab is given every 3 weeks during hospital visits by an injection into your thigh.

HOW LONG WILL STUDY TREATMENT LAST?

All patients will receive treatment for 24 weeks before having their breast surgery. During the study you will be asked to come into the hospital every couple of weeks until your planned breast surgery appointment and then for one final visit 4 weeks post-surgery.

WHAT IS INVOLVED?

If you decide to take part, you will be asked to have some tests to ensure you're eligible to participate. It is likely some of these tests would be done even if you decided not to take part in this study, and some

of these may have already been done. These tests will include measuring height and weight, blood tests and reviewing any medication you're currently taking. Once you have begun treatment you will be required to attend hospital visits for various assessments during the course of the study. You will have extra blood samples taken and an additional visit for a core biopsy in week 23. You will also have planned breast surgery and tissue samples taken.

The tumour tissue sample taken as part of your diagnosis will also be collected. Further information regarding study procedures and visits can be found within the full Patient Information Sheet.

SIDE EFFECTS

Like all medicines, palbociclib, tucatinib, letrozole and trastuzumab can cause side effects, although not everybody experiences them.

The most common side effects that have been recorded for these medications include reduced white blood cells, red blood cells or blood platelets, nausea and fatigue, diarrhoea and vomiting, indigestion, hot flushes, excessive sweating, joint stiffness, weight loss, dizziness and headaches and changes in blood pressure

A more detailed list of side effects is given in the full Patient Information Sheet and you should talk to your study doctor for more information about side effects.

CONTACT DETAILS

Contact details can be found on the full Patient Information Sheet. Please ask the study team as many questions as you wish, and read through the entire full Patient Information Sheet very carefully. Before you agree to take part, you must fully understand what the study involves, taking as much time as you need. Please feel free to discuss the study with your family, friends, study doctor and GP if you wish.

THANK YOU

Thank you for taking the time to read this summary information sheet. If this study interests you and you think that you might like to take part, please read the full Patient Information Sheet provided by the research staff.

3-PILLARS STUDY

SUMMARY PATIENT INFORMATION SHEET

3-PILLARS: The cyclin-dependent kinase 4/6 inhibitor palbociclib in combination with letrozole, trastuzumab plus tucatinib as neoadjuvant treatment for ER-positive, PgR-positive and HER2-positive early breast cancer

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