What are clinical trials?

Clinical trials are:

- **Research studies to answer scientific questions – such as whether a new investigational medicine is safe and effective and/or how does it compare to current best (or standard) treatment options?[1]**
- **A routine part of the work of specialist breast cancer centres**
- **Results can help doctors advise you about your treatment choices**

Stages of clinical trials

Preclinical research which can involve computer modelling and laboratory tests must be completed before clinical trials take place in humans. After this, there are four phases of clinical trials.[1]

Phase I trials: Find out the correct dose and schedule to administer the new medication. They also find out what the side effects are how the body gets rid of them.

- Small groups of healthy volunteers
- Test safety and possible side effects of an investigational treatment
- Determine how the investigational medicine should be used or delivered

Phase II trials: Start to collect data on how effective the investigational medicine is while continuing to look at safety, and find out what the most frequent adverse effects are.

- Involve more people than Phase I trials
- Assess safety and how well the new treatment works in people with the condition
- Usually lasts a few months to 2-3 years

Phase III trials: To evaluate if the new treatment is better than the standard one. Gather further information in different groups of people with the condition and test different dosages.

- Big studies
- Compare new medicine to placebo (a dummy medicine with no active ingredients) or standard treatment
- Results are sent to regulators who decide whether or not to approve the medicine
- Usually lasts several years

Phase IV trials: Occur after the drug is approved. Continue to collect more information about the new medicine's safety, efficacy and optimal use.

- Monitor effectiveness and safety in large populations to further understanding

Types of advanced breast cancer (ABC) trials

(sometimes called secondary or metastatic cancer)

A trial for ABC may look at new treatments or different ways of giving existing treatment. These could be different types of surgery, chemotherapy, endocrine therapy, biological therapy or radiotherapy.[2]

Placebo trials: One group involved in the trial is given a placebo drug, which contains no active ingredients.[2] The other receives the new treatment. For ethical reasons, patients will only be given a placebo if no other treatments are available to ensure they do not miss out on receiving treatment.

Blind studies: The patient will not know whether they are receiving the active treatment or the placebo.[2]

Double blind studies: In a double blind study neither the patient nor the doctor knows which treatment is being given. An independent committee can check.[2]

Randomised controlled: This is the opposite to a double blind study, where both the patient and the doctor know which treatment is being administered.[2]

Who can take part?

Each clinical trial has specific guidelines to who can take part. These are based on the investigational medicine, its pre-clinical data and who it might be suitable for.

Suitability for an ABC trial may depend on:[1]

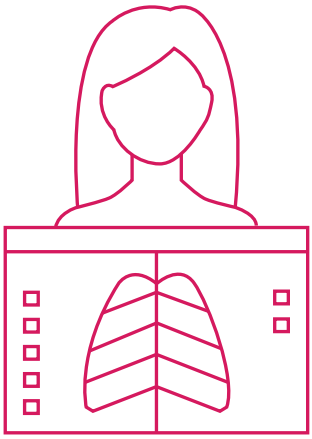
- Age
- Current health
- Location of metastasis – e.g. bone, lung, brain
- Types of tumour – e.g. ER+/- or HER2+/-
- Response to previous treatments
- Medical history

What are the advantages of clinical trials for a patient?[3]

- May benefit from a new treatment
- Opportunity to help improve ABC treatments for others and contribute to medical research
- Potentially more frequent appointments with doctors
- Extra tests and closer monitoring

Are there drawbacks to clinical trials?[3]

- Unexpected side effects, some of which may be serious, as all treatments have the potential to cause adverse events
- Treatment may not be more effective than the standard treatment
- May not respond to new treatment
- Additional hospital visits/tests may be inconvenient, increase travel costs or cause discomfort
- Increased focus on your ABC could increase anxiety/worry
- Depending on the structure of the trial you may receive placebo opposed to the investigational treatment



How to get involved

For most trials you will need to be referred by your doctor so speak to them first. They will know of any appropriate trials for you to take part in. Alternatively, patient groups often provide information regarding current trials on their websites.

You can find trials and further information at the following links:

www.cancerresearchuk.org/about-cancer/find-a-clinical-trial
www.clinicaltrialsregister.eu/
www.europadonna.org/research/

References

1. Novartis, What are clinical trials? Available at: https://www.novartisclinicaltrials.com/TrialConnectWeb/whatisclinicaltrials.nov [Last accessed: December 2016]

2. Breast Cancer Care, Types of Clinical trials. Available at: https://www.breastcancercare.org.uk/information-support/facing-breast-cancer/going-through-treatment-breast-cancer/clinical-trials/different-types-clinical-trial [Last accessed: December 2016]

3. Breast Cancer Care, Benefits and drawbacks. Available at: https://www.breastcancercare.org.uk/information-support/facing-breast-cancer/going-through-treatment-breast-cancer/clinical-trials/benefits-drawbacks [Last accessed: December 2016]

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