

CONVERT

Concurrent ONce-daily VERSus twice-daily RadioTherapy

A 2-arm randomised controlled trial of concurrent chemo-radiotherapy comparing twice-daily and once-daily radiotherapy schedules in patients with limited stage small cell lung cancer (SCLC) and good performance status.

Information for patients

This is an abbreviated version of the full patient information sheet for the CONVERT trial. If you are eligible for the study and interested in taking part your doctor will give you more detailed information to read and consider before you decide whether you wish to take part.

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What is the purpose of this research study?

Limited stage small cell lung cancer can be treated with a combination of chemotherapy drugs and chest radiation therapy, called concurrent chemoradiotherapy treatment. The purpose of this research study is to find out:

- What is the best total dose of radiotherapy to prescribe for small cell lung cancer?
- What is the most effective way of giving radiotherapy? Is it once or twice a day?

Who can take part?

You may be eligible to take part if you have recently been diagnosed with small cell lung cancer and your doctor recommends chemotherapy and radiotherapy treatment. There are also other criteria to determine whether this study would be suitable for you and your doctor will be able to check whether you fit these criteria, for example:

- This study is only for patients with small cell lung cancer (SCLC), not any other form of lung cancer.
- This study is for patients who have "limited stage" disease, which means that the cancer is confined to one area of the lung.
- This study is for patients with "good performance status". This means patients who may not be well enough to carry out strenuous tasks but are well enough to care for themselves, and carry out some light work/ house work, not so unwell that they are confined to a bed or chair
- This study is not suitable for patients who have already been treated with surgery or radiotherapy for lung cancer.

What will happen to me if I take part?

If you agree to take part, you will be asked to sign a consent form and your doctor will organise a number of tests to check if you are eligible for this study. The tests will include a physical examination, a chest X-ray, a CT scan of the brain, thorax and upper abdomen, a radiotherapy planning scan, blood tests and lung function tests. These tests are normally done as part of the routine tests for patients who are to be treated with concurrent chemoradiotherapy. Some patients may also require a bone scan or a pregnancy test.

If you are eligible you will be randomly allocated to once or twice daily radiotherapy. This is done by a computer, you or your doctor cannot choose the treatment. Once you have started the treatment you will be assessed weekly for any changes in your symptoms, any side effects of treatment and any changes in your blood tests. A CT scan will be repeated after chemoradiotherapy, then after 6 months of completing all the study treatment.

After completing treatment, you will be reviewed weekly until any side effects have resolved then 3 monthly until 1 year and 6 monthly thereafter. Follow up visits at more frequent intervals will be decided by your doctor. You will also be asked to consent to storage of tissue and blood samples for use now and in the future for research aiming to improve knowledge and treatment of small cell lung cancer. Consent to the storage of samples is optional, so if you prefer not to consent to this you may still take part in the research.

What are the treatments being tested?

The treatment being tested is radiotherapy. The trial is to compare a short course of radiotherapy given twice a day with a longer course given once a day. All patients will also receive standard chemotherapy treatment (cisplatin & etoposide). Chemotherapy will be administered by a drip for 3 consecutive days every 3 weeks for a total of 4 to 6 cycles. 3 weeks after starting chemotherapy radiotherapy treatment will be started with either:

- **Short course radiotherapy:** Radiotherapy delivered twice a day, Monday to Friday (excluding weekends) for three weeks. There will be an interval of 6 to 8 hours between each treatment, for example treatment will be given at 09.00hrs and 15.00hrs.
- **Long course radiotherapy:** Radiotherapy delivered once a day, Monday to Friday (excluding weekends) for six and a half weeks.

The radiotherapy treatment will take around 15 minutes each time.

What are the alternatives for treatment?

If you do not wish to take part in this study your doctor will tell you what alternatives are available. The alternative treatment will vary depending on your lung cancer doctor.

What are the side effects of the treatment?

Both chemotherapy and radiotherapy may lead to some side effects. The side effects are similar with both treatments, and similar to the side effects you might experience if treated for small cell lung cancer outside a research study. You will be given full information about the potential side effects when you discuss the treatment with your doctor, and will be given full written information to take away and consider.

What are the possible benefits of taking part?

We hope that both treatments will help you. However this cannot be guaranteed. The information we get from this study will help us to treat future patients with the same disease better.

Who can I contact for more information?

Your doctor can give you more information about CONVERT, or other research studies that may be relevant to you. Please ask your doctor for further information. If your doctor agrees that it would be appropriate for you to participate in CONVERT he/she will give you further information and you will be given time to consider this information before you decide whether or not you would like to take part. Before you take part you will be asked to sign a consent form, however if you change your mind about taking part you are free to withdraw your consent at any time.

For general information about all aspects of cancer, including clinical trials, the following resources may be useful:

[Cancer Research UK](#)

[Cancerbackup](#)