Kidney Cancer *The facts*

Clinical trials

Cryotherapy (cryoablation) for kidney cancer

Dietary advice for kidney cancer patients

Travel insurance for people with kidney cancer

Kidney Cancer UK

Kidney Cancer Scotland

All new drugs need to be vigorously tested to ensure they are safe and effective before they are licensed for use. Testing is conducted in the laboratory and in the clinic.

Drugs are tested in the laboratory to ensure they are pharmacologically safe for human use. They are then tested in the clinic by administration to humans in clinical trials.

The pharmaceutical company compiles the data collected during laboratory testing and clinical trials into a product license application. This application is submitted to the regulatory authority in each individual country to obtain a license to allow the pharmaceutical company to market and sell the drug.

There are four phases of clinical trials

Phase I
Clinical trials are the first studies in humans. These trials are conducted with small numbers of patients or healthy volunteers (usually male). They are used to investigate the most effective dose of the drug in humans and to determine what side-effects are most likely to occur.

Phase 2
Clinical trials investigate the safety and efficacy of the drug, in larger numbers of patients (100's) with a focus on the effectiveness of the treatment at different doses and its safest in the target patient population. Usually, when phase II is completed the pharmaceutical company will decide whether the safety and efficacy of the drug in the target patient population warrants further development. The drug will only be taken into phase III development if there is a very good chance of the drug meeting the strict safety and efficacy guidelines stipulated by the regulatory authorities.

Phase 3
Clinical trials involve large numbers of patients (1000s), usually on a global scale, and are used to compare the efficacy and safety of the new drug with either the standard existing treatment or placebo (dummy treatment). These studies are usually randomised and blinded so that the patients (and the medical and nursing staff in the case of double-blind clinical trials) do not know which treatment they are receiving, to avoid a biased interpretation of the results. Data obtained from phase III clinical trials are used to demonstrate the benefits of the new treatment over existing treatment or placebo.

Phase 4
This type of trial is done once the drug has been granted a liscence. The main reason for running phase 4 trials is to find out; more about side effects, what the long term risks and benefits are and how well the drug works in the wider population.

Who conducts clinical trials and where do they take place?

Clinical trials involve a number of different organisations. Often, clinical trials are designed, planned and sponsored by a pharmaceutical company or a public health agency. These organisations may subcontract the implementation, monitoring and reporting of clinical trials to a contract research organisation (CRO). The design, monitoring, analysis and reporting of clinical trials require specialised scientific expertise, contributed by the staff employed by the pharmaceutical company, the health agency, or the CRO.

Clinical trials are conducted in hospital departments, GP surgeries, or specialist phase I units, depending on the phase of the trial and the patient population under investigation. There will be a team of doctors, scientists, nurses, and other medical and healthcare professionals, running the clinical trial, which will be led by a doctor with a number of years research experience (the principal investigator).

Before a trial can start, the regulatory body of the country where the trial is taking place, to ensure strict regulatory guidelines are being followed in the design and planned conduct of the trial, reviews it. It is then reviewed by an Ethics Committee (or Ethical Review Board) to ensure that the patient's or volunteer's rights are protected, and the highest standards of clinical practice will be observed to ensure the safety of the patient or volunteer.

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Deciding to participate in a clinical trial

When deciding whether to take part in a clinical trial, you should be clear about the purpose of the clinical trial and what is expected of you. You need to consider the following fully before you enrol in a clinical trial:

- You will be cared for by doctors and nurses with detailed knowledge about the latest treatments for your condition.
- You will be monitored very closely during the trial and may benefit from additional testing that would not normally be carried out in routine clinical practice.
- You will be given the opportunity to be one of the first patients to benefit from the new treatment under investigation; if you are not responding well to current therapies, participation in a clinical trial may give you access to a treatment that will work better for you.
- However, you may experience unexpected side-effects to the new treatment and/or it may not be an effective treatment for you. The new drug may prove to be less effective than current available treatments.
- Close monitoring of the trial may result in more frequent hospital visits and more testing than would occur if you were not on the clinical trial. This could be disruptive to your life.

You should discuss any concerns or issues you have regarding your health and care during the clinical trial with your doctor before enrolling. It is very important to be fully informed about the purpose of the clinical trial, potential benefits and side effects of taking the new treatment, and what is expected of you in terms of hospital visits and tests during the clinical trial.

When participating in a clinical trial you will always be asked to sign a consent form to indicate your agreement to take part, and that you are fully informed about the treatment under investigation and what is expected of you during the trial.

You have the right to withdraw from a clinical trial at any time, and you do not have to give an explanation. Your care at the hospital or clinic will not be affected in any way and you will be offered current, existing treatment for your condition.

All information collected during a clinical trial, including your personal details and case notes, will be kept strictly confidential. The organisation responsible for analysing and reporting the results of the trial will identify your test results and details by a number and your initials only.

Help our cause

We receive no government funding and are dependent on raising money from other sources. Contributions made to Kidney Cancer Scotland will stay in that country. Please include Gift Aid to your donation. You can download the Gift Aid form from our website or contact us on **01223 870 008.**

If you would like to make a donation, you can do so in the following ways:

1. Make a donation online by visiting **www.kcuk.org.uk/donate/**

2. Send a cheque made payable to **'Kidney Cancer UK'** or **'Kidney Cancer Scotland'** to: **Freepost KIDNEY CANCER UK** (no need to add our postal address)

3. Send a donation to our bank account with your name as a reference

   Kidney Cancer UK (Barclays)
   Sort code 20-17-35 Account 80098094

   Kidney Cancer Scotland (RBS)
   Sort code 83-20-22 Account 11896991

4. Make a credit or debit payment (except Diners) on the phone, by calling **01223 870 008.**

5. Make a legacy. Please contact us about the best way to do this.

If you would like to offer your support in other ways, we would be very pleased to hear from you.

Contact us

Kidney Cancer UK
01223 870 008
Monday – Friday 9-5pm

www.kcuk.org.uk

Kidney Cancer Scotland
0141 428 3494
Monday – Friday 9-5pm

www.kidneycancerscot.org

0800 002 9002
KIDNEY CANCER CARELINE
Here to help

A dedicated **free** telephone helpline that provides support and encouragement to kidney cancer patients, their families and carers.

0300 102 0101
KIDNEY CANCER COUNSELLING
Here to support

The UK's first dedicated kidney cancer counselling service. Visit our website and search 'counselling' or call our **free** counselling service.

Last reviewed: January 2019. Next review: 2020.

Company No. 0593 7304. Registered charity England (No. 1120 146) and Scotland (SC043642).

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