

King's hepatitis B cure programme

Information for patients

King's College Hospital is starting clinical trials of potential cures for hepatitis B in 2020. This leaflet explains how these trials work and how you can get involved.

www.kch.nhs.uk

What is chronic hepatitis B virus (HBV)?

HBV is a virus that infects your liver and is in your blood. If you have this infection for more than six months, we call it chronic hepatitis B or chronic HBV.

About 240 million people in the world have chronic HBV. About a third (30%) of those with the disease have other health problems caused by HBV.

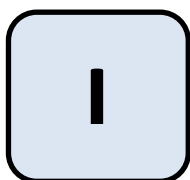
It is often called a silent disease because you may have no symptoms, even if you have been infected for many years. But it can still be causing damage which leads to the scarring of the liver (cirrhosis). This can cause liver failure and liver cancer (hepatocellular carcinoma).

Although chronic HBV is not currently a curable disease, taking antiviral medications can control the virus and reduce liver damage.

What is a clinical trial?

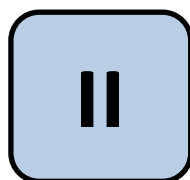
Clinical trials are a way of testing drugs or treatments to see if they are better than those currently available.

People may want to consider taking part in a clinical trial if there is no cure for their condition – such as chronic HBV – or to have new treatments that are not currently available on the NHS.



Phase 1

Early phase 1 (1a) trials use healthy volunteers to **assess safety**. Later phase 1 studies (1b) use patients and can involve whole day appointments in a clinical trials facility.



Phase 2

By phase 2, the drug being tested will have been proven to be safe in the short term. Phase 2 trials assess the drug's **side effects** and **efficacy (how well it works)**.



Phase 3

Phase 3 trials assess the drug's **side effects** and **efficacy (how well it works)** in a larger number of patients than the phase 2 studies.



Phase 4

Phase 4 trials happen after a drug has been licensed for use. These studies look at the **long-term effects** of a drug.

Will I be accepted onto a clinical trial if I agree to take part?

Unfortunately, you cannot automatically enrol onto a clinical trial. You must meet the inclusion and exclusion criteria for each trial. These are measurements or conditions that you can or cannot have to take part. They might include your age, gender and weight, and whether you have diabetes, other viral blood infections or a history of cancer.

What do I need to think about before I agree to take part?

There are two important things to consider before agreeing to take part in a clinical trial:

- **Are you planning to start a family?** Depending on the type of drug you are given, you may have to avoid conceiving a child during the trial and for a period of time afterwards because of safety concerns for the baby. Your doctor will be able to tell you how long you will have to wait before trying for a family and advise you about contraception.
- **Are you planning to go on holiday?** You may not be able to go abroad during a trial because you will need to come for regular check-ups at King's College Hospital.

What clinical trials are happening at King's?

As a King's patient, you have an opportunity to be involved in early stage (phase 1 and 2) or later stage (phase 3 and 4) trials of new treatments. These include:

1. Medications which block or reduce the replication of the HBV

These are similar to the antiviral drugs we currently use but they have an improved ability to increase the chance of your immune system clearing the hepatitis B virus.

How do I take the drug?	In what phase of the trial?	Are there any side effects?
Tablets	Phase 2/3	Minimal side effects

2. Medications which boost your immune system to clear or control HBV

a. Vaccines are used to prevent people from becoming infected with diseases, but special therapeutic vaccines work in patients with HBV by triggering a boost in their immune systems which causes the body to react towards the virus.

How do I take the drug?	In what phase of the trial?	Are there any side effects?
Injections	Phase 1	Few side effects seen so far

b. Immune system boosters aim to wake up your sleeping immune system – which is weakened by chronic HBV – and use your body's own defences to fight against the virus.

How do I take the drug?	In what phase of the trial?	Are there any side effects?
Tablets or injections	Phase 1 or 2	Mild side effects

3. Medications which disrupt the production of viral proteins and the genetic information of the virus.

These disrupt the virus's genetic information and prevent its production. You are given these medications as an injection and they have shown promising results in early tests.

How do I take the drug?	In what phase of the trial?	Are there any side effects?
Injections	Phase 1 or 2	Minimal side effects

When will these medications be available at King's?

They will be available as part of clinical trials at King's College Hospital in 2020. They may be tested alone, combined together or taken along with your current antiviral therapy.

Please let your doctor or nurse know if you are interested in taking part in clinical trials.

Important information about taking part in clinical trials

We will always do our best to provide the best clinical care for you, but clinical trials require you to be focused. Your safety and understanding of the trial are critical. We will send you a detailed information sheet when an appropriate trial comes up, and then contact you to discuss it further.

Taking part in a clinical trial is your choice. If you decide not to take part it will not affect the care you receive.

For more information please use the following contact details:

Tel: **020 3299 3597**

Email: **kch-tr.livertrials@nhs.net**

PALS

The Patient Advice and Liaison Service (PALS) offers support, information and assistance to patients, relatives and visitors. They can also provide help and advice if you have a concern or complaint that staff have not been able to resolve for you. The PALS office is on the ground floor of the Hambleton Wing, near the main entrance on Bessemer Road - staff will be happy to direct you.

Tel: **020 3299 3601**

Email: **kch-tr.PALS@nhs.net**

You can also contact us by using our online form at www.kch.nhs.uk/contact/pals

If you would like the information in this leaflet in a different language or format, please contact PALS on 020 3299 1844.