

Are you interested in helping find out if treatment for COPD can be improved?

**COPD - Chronic Obstructive Pulmonary Disease
(also known as chronic bronchitis or emphysema?)**

We would like to tell you about a new study (called BICS) because we think you might be eligible to take part, but you don't have to take part if you don't want to.

This research study is trying to find out if the beta-blocker bisoprolol reduces the number of COPD flare ups (also known as exacerbations). Beta-blockers have been used to treat heart conditions for over 30 years. There is some evidence that people who have COPD and who take beta-blockers are less likely to have flare-ups. In our study, we want to investigate whether people with COPD who are started on bisoprolol, are less likely to have flare ups.

w3.abdn.ac.uk/hsru/bics



Funded by
NHS
National Institute for
Health Research

What's special about the study?

We are using a well established heart drug (called bisoprolol) to try and reduce the number of flare ups people with COPD have.

The study is funded by the NHS through one of its research programmes.

We would like about 1600 people with COPD to take part.

What would taking part involve?

Taking extra tablets each day for one year. The tablets will be slowly increased during the first few weeks.

Having seven appointments/visits over a year at a local GP or hospital. The visits are similar to COPD clinic visits. We can help with travel costs.

Continuing to take your normal medicines.

For more information about the study, or to talk to someone about taking part, please contact your local study team or the main study office on 01224 438178.

Your local study team is:

Teign Estuary Medical Group

Principal Investigator: Dr Tamsin Venton
Research Practitioner: Lydia Hall
Tel: 01626 770955

**Thank you for taking the time to read this information.
You can read more about this study on the other side of this leaflet**

Bisoprolol in COPD study (BICS)

What is Bisoprolol?

Bisoprolol is a tablet called a beta-blocker, it is used very widely to treat heart disease and is safe to use in COPD.

What will happen to me if I take part?

- To find out if bisoprolol reduces the number of COPD flare ups we are comparing the effect of bisoprolol against the effect of a placebo 'dummy treatment', which looks like the genuine medicine but contains no active ingredient.
- Each person in the study is put into a group selected randomly by a computer (like tossing a coin).
- Half of the 1574 people will take bisoprolol and half will take the placebo for a year.
- To make sure that the true effects of bisoprolol are being studied neither you nor your doctor will know which treatment group you are in (although, if your doctor needs to find out he/she can do so).
- If you are interested in taking part we will send you more information and make plans to see you in a local General Practice or local Hospital at a time convenient to you.

Your commitment includes:

1. Being seen on 7 occasions at a local General Practice or Hospital over the year. We can help with travel expenses. At these appointments we will ask you to do some of the following depending on the visit.
 - Discuss the study and sign a consent form.
 - Fill in a questionnaire on how COPD affects you.
 - Do some blowing tests as in a normal COPD clinic.
 - Let us measure your height, weight, pulse rate and blood pressure.
 - Tell us how many flare ups you have had since last appointment/visit.
2. Taking the study tablets for a year and making a note of any flare ups of your COPD and how they are treated by your GP. Supplies of study tablets will be sent by courier to your home address.
3. Continue taking all *of your normal medicines*. If you need to go to your GP for treatment you should go, any flare ups of your COPD can be treated as they normally would.

What are the possible disadvantages of taking part?

- Although most people tolerate bisoprolol well, some people can develop side effects. The side effects of bisoprolol are well known.
- *We hope to reduce side effects by slowly increasing the dose of study tablets at the start of the study to find the best dose for you.*
- If side effects do develop then they will go away when the dose of study tablets is reduced or stopped.
- If you are interested in taking part we will give you more information on possible side effects and how commonly they occur.

What are the possible benefits of taking part?

We cannot promise the study will help you, but we expect the information we get from this study will help improve the treatment of people with COPD. We will investigate whether taking bisoprolol will reduce the number of flare ups in people with COPD, and if it does, whether it reduces the need for antibiotics and steroids and reduce hospital admissions for COPD. The lung function measurements we make during the study will be useful to your GP.

Contact for further information

If you have any questions or are interested in taking part in this research please let us know and we will send you more information. Our contact details are on the other side of this leaflet and there is information in the letter about how to contact us.

Thank you for taking the time to read this information leaflet.

We hope that you have found it useful in deciding whether or not to take part in the BICS study.