CF STORM
CLEARING THE AIR

CF STORM Young Person (12-15 years old) Information Sheet

Why are we doing the CF STORM study?

- A research study is what doctors do when they want to learn about something, or find out something new.
- As Kaftrio™ is a new medicine we all need to learn how it could make changes to your other CF medication. We can do this with a research study. CF STORM stands for Streamlining Treatment Or Reducing Medication.

What is the CF STORM study?

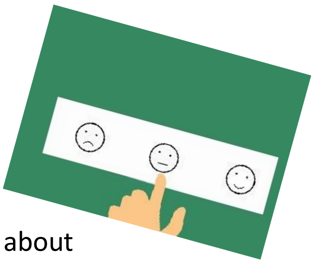
- CF STORM is a study that looks at whether stopping certain daily nebulisers (dornase alfa, hypertonic saline or both) is safe for people like you taking the new medicine Kaftrio™.
- The study will run for a year (52 weeks) collecting feedback from people as they go about their daily lives.

Why me?

- Because you:
  - have been taking Kaftrio™ for 3 months.
  - use daily nebulisers.
  - are part of the UK CF Registry (a list of people living with CF and their health data).
  - do lung function tests called spirometry (at home or in clinic).

If I take part, what do I have to do?

- If you choose to take part you should not need any extra appointments, as the study is designed to fit in with your usual care. The study appointments can be carried out on the telephone/video call, if that's the way they are normally held. It is very important that you tell your Mum, Dad, or the grown up looking after you and your Doctor if you are feeling poorly.



- During the study your Mum, Dad, or the grown up who looks after you will receive links (by email) to a questionnaire for you to complete. It will ask how you are generally feeling at that time (this questionnaire is called an EQ-5D-5L). We will ask you to complete the first EQ-5D-5L just after you agree to take part in the study, and again at 17, 34, 50 weeks in – so four time in total.
- Your Doctor will also provide you with a questionnaire to ask how you are feeling about your CF (called a CFQ-R). We will ask you to complete this questionnaire twice – once when you agree to take part in the study and again at 50 weeks in. Your Doctor may already ask you to complete this questionnaire as part of your usual care.
- Your Mum, Dad, or the grown up who looks after you will receive three emails (at 12, 26, 39 weeks in) containing a link to a survey to ask about the medicines you are currently taking for the study.
- If you have a nebuliser that can record when it is used (such as an iNeb), we may ask you if we can download the information that it collects at your clinic visits. This will help us understand the results of the study.

How will my medicine change if I take part?

- During the study you will be asked to join a group so you either:
  1. continue taking your daily nebulisers as usual.
  2. **or** stop taking the following nebulisers:
     - dornase alfa (which you may know as DNase or Pulmozyme®)
     - hypertonic saline (which you may know as Nebusal® or MucoClear®)
     - or both dornase alfa and hypertonic saline
- You will carry on taking all your other medicines as usual.
- You won't choose which you join. A computer will decide this.

Do I have to take part?

- No, not at all. It's completely up to you! If you don't want to take part, just tell your Mum, Dad, or the grown up who looks after you. It won't change how you are looked after by your CF team.
- If you decide to take part, that would be really helpful. If you change your mind, that's OK as well. You don't have to tell us why you changed your mind.

Are there benefits and risks of taking part?

- If you are asked to stop taking your daily nebulisers you will have to take less medicines in total each day. However, it may prevent your lungs from working as well as they should.
- There will always be a member of you CF team that you or your Mum, Dad, or the grown up who looks after you can phone if you have any worries.

Who will my information be shared with?

- We will ensure your information is correct and that it is shared in a way that only those who need it to answer the study question will have access to it. Your information may be helpful to researchers running other studies. These researchers may be from universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used in accordance with the UK Policy Framework for Health and Social Care Research, or equivalent standards.

Who is running the CF STORM study?

- Alder Hey Children's Hospital NHS Foundation Trust is responsible for managing this study. They have asked that the day to day running of the study is carried out by a team based at the Liverpool Clinical Trial Centre (LCTC, part of the University of Liverpool). There are two doctors running the study, based at University of Liverpool and University College London. They are supported by a large team from across the UK, including CF doctors looking after adults and children, and health economics researchers from University of East Anglia. LCTC work with the UK CF Registry who provide the database for your CF Team to record your data on.
- The money needed to set up and run this study has been provided by National Institute for Health Research-Health Technology Assessment programme.

What do I do if I have any questions?

- Your Mum, Dad, or the grown up who looks after you have been given lots of information. If you have any questions you should contact your CF Team who care for you.
- You can also check out our website:
  cfstorm@liverpool.ac.uk

Thank you for reading this information!