BEACON: Best systemic treatments for adults with atopic eczema over the long term

REC Reference 23/LO/0224

Participant information sheet

We would like to invite you to take part in this research study called BEACON

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please **take time** to read the following information carefully. Discuss it with friends, family or your GP if you wish.
- You are free to decide whether or not to take part in this trial. If you choose not to take part, this will not affect the care you get from your healthcare team.
- This leaflet is in two parts: we suggest that you read **Part One** first and if you are interested in taking part, continue to read **Part Two**.
- If you decide to take part there are more information leaflets about the treatments you may receive
- **Ask us** if there is anything that is not clear or if you would like more information.

Contents

If you have any questions about the study, please contact:

Study Doctor:

Research Nurse:

Or visit www.beacontrial.org

Summary

- You are being invited to take part in a trial to investigate how effective systemic treatments (medications taken by mouth or injected) are for more severe adult eczema. These treatments include dupilumab, methotrexate, abrocitinib, and ciclosporin, all of which are used in routine NHS practice and can help eczema.
- You will be randomly assigned to receive one of these treatments for 6 months. This will be an injection of dupilumab every two weeks, an injection of methotrexate every week, an abrocitinib tablet every day, or ciclosporin tablets every day. There is no placebo "dummy" medication in this trial, and you will know which treatment you are on. Treatments will be prescribed, and you will be followed up in line with routine NHS care.
- You will be able to increase the dose of treatment after 3 months for drugs where that is an option (methotrexate and ciclosporin) and you will be able to switch treatment at 6 months if your treatment is not effective. Treatment will then continue for a further 6 months (12 months in total).
- If you agree to take part, you will need to stop all UV light related treatment or systemic treatment (medications taken by mouth or injected) that you are currently taking for your eczema but can continue topical treatment (creams/ointments)
- Everyone participating will make a real difference to our knowledge of how effective these eczema treatments are and importantly, how they compare.

Part One: I am considering taking part

1. Why are we doing this study?

Mild eczema can usually be controlled with creams or ointments. More severe eczema is often treated with medications taken by mouth or injection (often called systemic therapies). These medications act on different parts of the immune system.

Recently, many new systemic treatments have been introduced. **We are running this trial to find out which systemic therapy is the most effective and best tolerated. This will help people with eczema and their doctors select the best treatment, first time**.

2. Why am I being asked to take part?

You have been invited to take part in BEACON because you have more severe eczema that could benefit from systemic treatment.

3. How will the treatments be tested?

The best way of knowing whether one treatment is better than another is by carrying out a type of research called a randomised controlled trial.

A randomised controlled trial compares two or more groups of people, each group receiving a different treatment. If you take part in the study, a computer will randomly allocate you to a treatment group. This allows a fair comparison between the treatments to see which one works best.

4. How will my treatment differ from normal NHS care if I take part?

The treatments involved in this study (dupilumab, methotrexate, abrocitinib, and ciclosporin) are used to treat more severe eczema in routine NHS practice. The trial visits and safety checks in this study have been designed to mirror routine care as closely as possible. Some specific differences in the trial though are that:

a) You will be randomised to receive one of the four therapies. If there is good reason to exclude a treatment then this will be considered; otherwise, there will be no good clinical reason for treatment choice, hence the need for this study. On average, for every 4 people joining the study, 1 will be allocated to dupilumab, 1 to methotrexate, 1 to abrocitinib, and 1 to ciclosporin. If your study doctor feels that any of the treatments are not appropriate for you it may still be possible to take part. They will discuss this with you, and you would then be randomly allocated to one of the remaining treatments. There is no placebo (or “dummy”) treatment in this trial, everyone will receive an active treatment. Further details about the treatments are

given in the **treatment specific patient information sheets**.

b) You will be asked to complete some additional study assessments including, for example, questionnaires to assess the symptoms that you experience from your eczema, the impact that it has on your quality of life and your healthcare usage.
c) You will be asked to complete a survey at the start and end of the trial that will ask about any eczema treatment you might have taken previously and about your knowledge, expectations, concerns and preferences for the treatments used in this trial.
d) For those randomised to dupilumab you will have two additional visits over the one-year trial period compared to standard NHS practice to enable us to accurately and fairly assess the improvement in your eczema over time compared to the other treatments.

5. What will I need to do if I take part?

If you agree to take part in the study and sign the consent form, you will be assessed by an authorised doctor at your clinical site to ensure that you are suitable to take part. You will be randomised to one of:

1) Dupilumab - one injection every 2 weeks
2) Methotrexate - one injection every week
3) Abrocitinib – one tablet every day
4) Ciclosporin – tablets every day (also available in liquid form)

You will need to attend clinic regularly (7 study visits plus up to 6 additional safety blood tests/ blood pressure measurements) so that your study team can assess how your eczema is responding to treatment. You will be provided some reimbursement (up to £12) for travel costs to attend the 7 study visits. This study will be assessor blind, which means that you and your doctor will know which medicine you are taking, but the person assessing the severity of your eczema will not know which treatment you are taking. This is to ensure that we come up with a truthful answer on which medicine is best.

Safety checks, for example blood tests, urine tests and blood pressure readings, will be performed as per standard NHS practice and some of these can be performed at your local GP practice if that is easier for you. Your participation in the study will last for 12 months.

Some of the treatments may be harmful to a baby in the womb, therefore for females it is important not to conceive whilst on therapy and to use effective contraception throughout the study. Males on methotrexate will also need to use effective contraception (not relevant to dupilumab, abrocitinib, or ciclosporin). Both males and females need to continue effective contraception for a further 6 months after stopping methotrexate, and females need to continue effective contraception for at least 1 month after stopping abrocitinib Males cannot donate sperm whilst on methotrexate or within 6-months of stopping treatment. Females cannot breast feed whilst on methotrexate or

abrocitinib.. Your doctor will discuss this with you and if, for example, you cannot take methotrexate it is still possible to take part and be randomised to one of the other treatments.

6. What are the possible advantages of taking part?

The therapies involved in BEACON are all used in standard NHS practice. These include the very latest eczema treatments which are not available through the NHS if you have not already tried standard treatments. It is therefore possible that by taking part in BEACON you will see benefits to your health including a reduction in your eczema symptoms and signs.

You will be monitored very closely by the clinical study team and will have access to a dedicated study team. Close monitoring and contact will allow the team to answer any questions or concerns you have relating to your care and wellbeing throughout the study.

We hope that the information that we get from this study will help us to provide more effective and better tolerated treatment for people with eczema in the future.

7. What are the possible disadvantages and risks of taking part?

The main disadvantages of the trial are that you will need to agree to be randomised to treatment and to complete some additional study assessments (*e.g.* online questionnaires) which may take up to 30 minutes ahead of each visit. Your local study team will always try to streamline your visits as much as possible, but you will need to allow up to 2 hours for each study visit. If you are randomised to receive methotrexate or dupilumab you will need to learn how to self-administer treatment injections which may be time consuming. Some specific considerations include:

i) Risks from taking the treatments

The trial treatments are being used with the aim of improving your eczema however they may not help or may even worsen your symptoms. You may also experience side effects from taking the study medicines which are described in the accompanying **treatment specific patient information sheets**.

ii) Risks from stopping existing treatment to go into the study

You will need to stop any existing phototherapy or systemic treatment for your eczema prior to entering this study which may cause a slight deterioration of your eczema. **Moisturisers, topical steroids and topical calcineurin inhibitors are however allowed throughout the study** where needed. You will be closely monitored all the time so that in the event of new symptoms and signs of eczema, assessment and treatment can be given promptly by specialists experienced in caring for eczema patients.

iii) Risks related to having blood taken

Blood tests may be uncomfortable and cause some bruising or light headedness. On very rare occasions infection can arise as a result of having blood taken. To reduce discomfort all required samples at any one visit will be taken at the same time by a clinical professional trained and experienced in taking blood from patients.

iv) Live vaccines

Most vaccines do not contain living bugs, but some still do, and these are called "live" or "live-attenuated" vaccines. You cannot receive live or live attenuated vaccines (*e.g.* nasal flu, yellow fever) whilst on treatment and for 3-12 months after the last dose of study drug (this will be confirmed by your study doctor dependent on the study drug taken). If you have been advised to have a vaccination, please discuss this with your study team prior to proceeding so that they can check the nature and safety of the vaccine for you. No current COVID vaccines are live, but if you plan to have one check with your doctor and let the study team know.

8. Do I have to take part, and what if I change my mind?

Participation is completely voluntary, and it is up to you whether you wish to take part or not. If you decide to take part, you are free to withdraw from the study at any time and without giving a reason. This will not affect the medical care you will receive.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

If you decide to withdraw from the study, you may request for the destruction of samples that have not been tested yet.

Part Two: I would like to know more

9. Will I need extra tests?

Dupilumab, methotrexate, abrocitinib, and ciclosporin are routinely used in the NHS to treat more severe eczema. It is standard practice to have a number of tests performed before you start any treatments like this to check that they will be safe for you. Examples include a clinical examination, blood tests, urine tests and blood pressure checks. These same tests will be performed in this study. Because the study treatments work by targeting the immune system, so can make some people more prone to infection, blood testing includes checking you for some viruses including hepatitis and HIV and bacteria including tuberculosis. If active infectious hepatitis B or C or tuberculosis is confirmed during these tests, it will need to be reported as per standard practice. If you are female, you will require a pregnancy test before starting treatment.

Once on treatment you will undergo safety checks including blood tests, urine tests and blood pressure checks as per normal practice for the medicine that you are on. Approximately 10-20ml of

blood (2-4 teaspoons) will be taken at each visit. This is a very small amount of blood (your body contains 5000mls of blood) and will not adversely affect you in any way.

The only additional blood tests that you will require for the study that you would not need in routine practice are three samples at months 1, 3 and 6 to check methotrexate levels (only relevant to those randomised to methotrexate, to understand if these match with your eczema severity) and, if you consent, a one-off blood sample for DNA (optional, see section 18).

10. What will happen during the study?

The BEACON trial procedures are summarised in **Figure 1**, below.

i) Checking you are suitable for the trial

As per routine practice, you will be reviewed by your study team to check that you are suitable to take the study treatments (called a screening visit). If you are receiving UV light treatment (phototherapy), using tanning beds, taking Chinese medicine in any form, or taking systemic treatment for your eczema you will be asked to stop before starting on the trial treatment – this is known as a "wash out". Your study doctor will explain how long the wash out will be depending on the treatment(s) you are currently using. For example, the wash out period can be up to 3 months long if you are on an injection treatment for your eczema, or as short as 4 weeks if you are receiving phototherapy or tablet treatment. You will be monitored to make sure that your skin does not deteriorate too much in the run up to starting the trial medication and that it is still safe for you to participate. **There is no "wash out" required for creams and ointments so you will be able to continue using those as required throughout the trial**.

The study team will set you up on a web-based system called DrDoctor so that we can send you links to the assessments to be completed before or during trial visits. These will include a set of questionnaires assessing the symptoms that you experience from your eczema, your perception of disease control, impact on your quality of life, mood, daily function and what healthcare services you are using (for example visits to your GP or Dermatologist). These assessments can be completed on your phone, laptop or tablet. Please try to complete these as accurately and honestly as you can. You will also be sent a link to a survey that will ask about any eczema treatment you might have taken previously and about your knowledge, expectations, concerns and preferences for the treatments used in this trial.

Your GP will be kept informed of your participation in the trial. By consenting to take part, you will agree to us sharing your progress in the trial with your GP, as needed for your clinical care.

ii) Starting treatment

If your screening visit goes well and you are suitable to take part in the trial, you will attend a second visit when you will receive your medication and start treatment. If randomised to an injection

therapy, the clinical study team will show you how to administer the medication and will provide whatever support you need to gain confidence in injecting the medication yourself so that you are happy to continue at home. You will be able to contact the study team if you have any problems or concerns with the injections.

An independent assessor will look at your skin before you see a member of your study team at each outpatient clinic visit. It is important you do not talk to the assessor about the medication that you are on or any other aspects of your involvement in the trial and progress. This ensures that the assessments are performed independently (i.e. blind) from any knowledge about problems or benefits you may have noticed yourself, ensuring we can be confident of the results of the trial. The independent assessor may not talk to you beyond a couple of set phrases as part of trial procedure, they are not meaning to be rude! Please just show them your skin so that they can carry out the trial assessments (determining the severity of your eczema).

iii) Continuing treatment

You will take tablets or self-administer injections at home for 12 months dependent upon which arm you are randomised to. A member of the study team will provide you with all the necessary instructions, support and supplies you need. This will include a sharps bin to dispose of used needles/medication which can be returned to your GP or local pharmacy (depending on local guidance), or to the study team when full. If you miss a dose do not take a double dose but let your research nurse or doctor know as soon as possible. If you are worried about any aspect of your involvement in BEACON at any time don't wait for your next trial visit. Use the contact details in this leaflet to get in touch with the study team immediately.

You will be seen in the outpatient clinic at months 1, 3, 6, 9 and 12 similar to routine NHS care for people on these treatments. Visits will include an assessment of your symptoms, completion of questionnaires about how your skin affects you and your daily life (these will be sent to you electronically via DrDoctor one week ahead your appointment so you can complete them remotely in advance), a clinical examination and routine blood tests.

At each visit the trial team will ask about any new or changing medical problems and medications used since your previous visit. It is important that you let your study team know if you have felt unwell, needed to visit a doctor, changed any existing medications, or started any new medication.

iv) Changes in treatment dose and treatment type on the study

As per routine clinical practice, dependent on your progress and how well you are tolerating the treatment that you are on, there will be an option to increase the dose of methotrexate or ciclosporin after 3 months (dupilumab and abrocitinib come in one standard fixed dose). This is to ensure that we optimise your chances of seeing an

improvement in your eczema. Likewise, at 6 months, depending on your response to treatment and how you have found it, you will either continue treatment for a further 6 months if all is going well, or switch to another treatment in line with NHS practice (methotrexate to dupilumab, ciclosporin to dupilumab, dupilumab to methotrexate, abrocitinib to methotrexate) for 6 months, again to try and optimise your chance of seeing an improvement during your time on the trial.

v) End of study

Your final trial visit will be at 12 months. At this point your study doctor will talk to you about how you have found the study treatment. They will consider which medicine you are on at the end of the trial, how effective it has been, how well you are tolerating it and advise you regarding ongoing treatment options. You may be able to continue the treatment that you are on. Two possible exceptions to this are (1) if you have been on ciclosporin throughout the trial (12 months), when a switch in treatment is often advised, and (2) if you have been on dupilumab or abrocitinib throughout the trial (12 months) and do not meet National Institute for Health and Care Excellence (NICE) criteria for continuation of treatment in the NHS, which might mean you need to try another medicine before returning to dupilumab / abrocitinib. Your study team will ensure that there is a full handover of your progress to the clinical team that takes over your care (if a different team) so as to optimise your chances of maintaining or improving any control you may have achieved during your time in the study.

You will also be sent a link to an online questionnaire that will ask you about your experience of taking the study medication, any difficulties associated with the medication, strategies that you developed to support taking the medication and any preference for the specific treatments in hindsight.

vi) Medications that you need to avoid whilst participating in this study

Whilst taking the trial treatment you may continue taking medication for other conditions as directed by your doctor or GP. You may also continue to use topical steroids or topical calcineurin inhibitors (e.g. tacrolimus) if needed. You must *not* however take the following medicines:

I. Oral or injectable forms of steroids such as prednisolone.

II. Systemic medications which may help your eczema: examples including azathioprine, mycophenolate mofetil,. upadacitinib, baricitinib, novel injection therapies for eczema (*e.g.* tralokinumab, lebrikizumab, nemolizumab) and any of the treatments involved in this trial (dupilumab, methotrexate, abrocitinib, or ciclosporin) which you have not been randomised to.

III. Any other therapies for eczema as part of another clinical trial

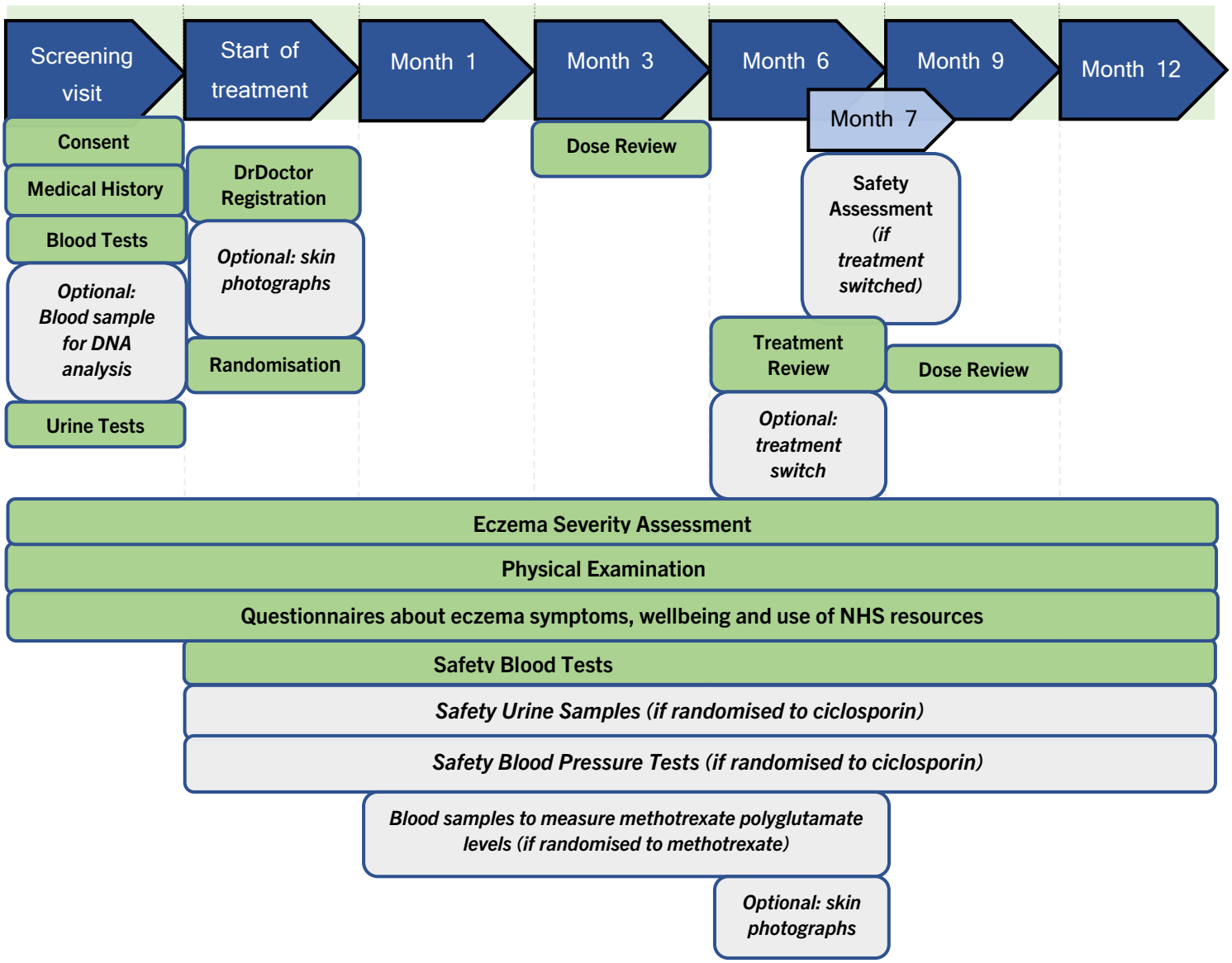

Figure 1 BEACON trial procedures

11. Who is organising and funding the study?

This research is funded by a grant awarded to the Programme Lead Professor Catherine Smith and Chief Investigator Dr Andrew Pink by the National Institute for Health and Care Research as part of its Health Technology Assessment Programme. The study is being sponsored by Guy's and St Thomas' NHS Foundation Trust and King's College London. The pharmaceutical company that makes injectable methotrexate (MEDAC Pharma) have agreed to provide the drug free of charge and are funding the testing of some blood samples to check how levels of methotrexate in the blood relate to treatment response. The pharmaceutical company that makes abrocitinib (Pfizer) have agreed to provide the drug free of charge and are

funding the incorporation of that treatment into the trial.

12. Is the study ethical?

This study has been reviewed and given a favourable opinion by the Health Research Authority (HRA) and the Harrow Research Ethics Committee, who protect the rights and interests of the participants. All of the drugs used in this trial are used to treat eczema in routine NHS clinical practice.

13. What will happen to any samples (blood, DNA) that I give?

If you are randomised to methotrexate some of your blood samples will be sent to laboratories at Guy's & St. Thomas' Hospitals to check your methotrexate levels. If you consent to providing blood for DNA it will be sent to St. John's Institute of Dermatology laboratories within King's College London for processing. Samples will be stored securely in accordance with the Human Tissue Act (2004) and national and local NHS Research Governance guidelines. These samples will only be used for scientific research related to skin disease. If you agree, we plan to store some of your blood samples in an ethically approved research bioresource (a bank of human tissue samples), and limited personal data in a secure, confidential database for the duration of this study and for future research into skin disease. If you do not wish to provide the optional blood sample for DNA, or want it to be stored in the bioresource, it will not affect your participation in the trial.

14. How will my personal information be used?

i) Will my details be kept confidential?

Your data will be processed under the terms of UK data protection law, including the UK General Data Protection Regulation (UK GDPR, 2018) and the Data Protection Act (2018).

- Guys and St Thomas NHS Foundation Trust and King's College London are the joint sponsors for this trial and will act as the data processors and data controllers for the trial.
- You will be given a unique study number which will be used to identify any samples and information collected during the research.
- All participant data collected will be pseudo-anonymised, meaning it has been processed in a way that ensures that you cannot be directly identified from it. Participant data will be stored on a password-protected database, or in a file that will be stored in locked cabinets with restricted office access at research sites.
- Research data collected will be entered into electronic databases including the InferMed Macro 4 system which is maintained on a secure server by the King's Clinical Trials Unit (KCTU). Database access will be strictly restricted through user-specific passwords

to the authorised study team members. Personally identifiable information such as name, email address, postal address, postcode, and NHS Number (or CHI number in Scotland) will not be recorded on the database.

- If you provide consent to be contacted to discuss taking part in the optional interview study (see section 17), your contact information (telephone number, email, postal address) may be sent to BEACON collaborators at the University of Nottingham by your local study team.
- Data relating to any samples given will be stored in a database developed and maintained by Guy's and St Thomas' NHS Foundation Trust that is held on a secure server behind the NHS Trust firewall. Identifiable information about you (e.g. initials, date of birth, ethnicity gender and NHS number) entered on this database will only be accessible to the BEACON study team members at your local hospital and the central BEACON study team at Guys & St Thomas' Trust. The system will be used for the purposes of tracking where blood samples are being stored and the results of bloods being analysed. We will also hold your data if you have given permission for us to do so, to invite you back for further investigation or request more samples.
- Data stored in the DrDoctor platform, which will be used to send you links to the assessments to be completed before your hospital visits, will include personal information about you including your telephone number which could be viewed by members of the study teams taking part in the BEACON Trial across NHS hospitals in England, Scotland and Wales.
- During the trial, authorised staff outside of your hospital will need to see information about you and view your personal and medical records. This is done as a check to ensure that the research is being done properly.
- The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.
- In case of an emergency and for your safety, the study doctor may have to disclose information about you and the treatment you are receiving for the appropriate medical management to be provided.
- We advise that you inform your private medical insurance provider (if you hold private medical insurance) of your participation in this study - this is a routine procedure for this type of research.
- The sponsor will keep identifiable information about you for at least 5 years after the trial has finished.

ii) Where can I find out more about how my information is used?

You can find out more about how we use your information at

- www.hra.nhs.uk/information-about-patients/

- our leaflet available from https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research
- by asking one of the study team
- by contacting Guys & St Thomas's Data Protection Officer, Nick Murphy-O'Kane: DPO@gstt.nhs.uk

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can lodge a formal complaint to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

15. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to your study team or the trial manager who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure by contacting your local Patient Advice Liaison Service (PALS) office. Details of your local office can be obtained by asking your study doctor, GP, telephoning your local hospital or looking on the NHS choices website (https://www.nhs.uk/using-the-nhs/about-the-nhs/your-choices-in-the-nhs).

Every care will be taken during this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

In the event something does go wrong, and you are harmed during the research due to someone's negligence, you may have grounds for legal action and compensation against the sponsors - Guys & Thomas NHS Foundation Trust and King's College London - but you may have to pay your legal costs. Guys & St Thomas NHS Foundation Trust maintains adequate insurance to cover any liabilities arising from the study.

16. What will happen to the results of the clinical trial?

We will inform the clinical and academic community by publishing results in medical journals and presenting at national and international conferences. We will inform people with eczema and interested lay public through presentations, webinars, infographics, and social media by working with the National Eczema Society and the wider media. We will work with NHS organisations, policy makers and guideline developers to ensure our research positively influences the management of people with eczema. We will provide a summary of the results of the study to all study participants.

17. Optional additional parts of the study that you may be asked to take part in

The following procedures are optional and opting not to consent to them will

not affect your medical care or the rest of your participation in the BEACON study.

Provide a DNA sample

You will be invited to provide a DNA sample to help us investigate whether people's genes affect how they respond to these treatments. In the future, if we can predict which patients are most likely to respond to each therapy based on their 'genetic makeup' we can tailor treatments more effectively. We would also like to use the samples to look at any new biomarkers or genes that are discovered in the future, so with your permission we will store your samples in a central biobank for potential further investigations into eczema. We may also want to contact you again for further information and/or samples. Unfortunately, we will be unable to share the individual results of any tests performed on these anonymised samples. We will only use the samples you provide to look at genes related to eczema, and other inflammatory disease research. We will not use your DNA for any tests to learn about your risk of developing any other disease.

Have photographs of your skin taken during the trial

We would like to ask you to have photographs taken of your skin by a researcher at your hospital site (according to their clinical photography protocol) at the beginning of the trial and after 6 months. Your photos will be confidentially uploaded to our secure database and will be stored in accordance with UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018 and will only be accessed by research team members with a legitimate reason to do so. If you can provide photos, we will use the photos to help develop accurate digital skin assessment methods. Only de-identified photographs, which have no content allowing for recognition (e.g. facial features), will be used in analysis and published in scientific reports, on the study website, or used in clinical presentations and educational materials, and/or in future research.

Take part in one-to-one interviews

You may also be invited to take part in two interviews with a member of the research team to hopefully enable us to optimise the study for future participants and help us understand how the results of the trial should change real world practice. One interview will occur near the start of the trial and one at the end of the trial. The first interview will focus on your experience of having eczema, your thoughts about participating in the trial, your knowledge and feelings about the different treatments involved and your expectations of those treatments. The second interview will cover your experience of being in the trial and on treatment, whether your expectations have been met or have changed and given your experience, your suggestions regarding future treatment use. If you change treatment after 6 months, we may ask you if you would be happy to have an additional interview at that stage.

The interview will be audio recorded, transcribed by a trusted service, and analysed by a member of the research team. Your personal data, audio recording and transcription will be encrypted and securely stored on a password protected computer. Your personal data will be known only to the researcher and will not be shared with anyone else. If you consent to being contacted about this, you will be provided with further, more detailed information by BEACON collaborators at the University of Nottingham via telephone, email, or post.

Provide blood and skin samples as part of a related scientific study, mySkinomics (not running at all sites)

You may be invited to participate in a related scientific study, mySkinomics, which would involve giving optional blood and skin samples. The main aim of the study is to better understand how the eczema treatments used in the BEACON trial work. We will find out how the blood and skin change before and after treatment using cutting-edge science. This means we will know, at a molecular level, how each cell is working and communicating with other cells. This information will help us to select individuals most likely to respond well to the treatments available already, and to design better, safer treatments for the future. If you are at a participating centre, you should have received further details about this scientific study at the same time you were given this information sheet.

Enrol onto a longer-term registry of eczema treatment

If you are at a participating centre, you will be invited to enrol into the UK-Irish Atopic Eczema Systemic Therapy Register (A-STAR) (https://astar-register.org/) to help us learn the long-term safety and clinical outcomes of systemic treatments such as those being tested in the BEACON study. This registry is being compiled by the British Skin Foundation and the British Association of Dermatologists. This would enable us to transfer some information we learn about you from this trial into the register and for them to keep in contact with you when you finish the BEACON study. You should receive further details about the registry once you are enrolled onto the study and about to start treatment.

To be contacted for future research

You will be asked if we can contact you in the future to invite you to take part in future research which we think you would be suitable for.

Thank you for taking the time to read this information leaflet and for considering taking part in the BEACON study.