



APRICOT

Anakinra for Pustular psoriasis: Response In a Controlled Trial

A Randomised, Double Blind, Placebo-Controlled Multicentre Clinical Trial

PARTICIPANT INFORMATION LEAFLET

- You are being invited to take part in a trial to investigate the effects of a medication called anakinra in palmo-plantar pustulosis (PPP).
- The purpose of the trial is to determine if an 8 week course of anakinra can improve the symptoms of PPP and to find out whether anakinra might be a much more effective treatment option for patients than the medicines currently available.
- Study participants will be randomly assigned to receive daily injections of either anakinra (the active drug) or placebo (dummy). You will have a 50:50 chance of receiving anakinra if you decide to take part.
- If you take part, you will need to stop all treatments that you are currently taking for your PPP. If you are on injection treatments this 'washout' period may be as long as 3 months.
- Everyone participating will make a real difference to our knowledge of PPP and potential treatments.
- If you are interested to learn more about the study, please read the rest of this information leaflet where we explain what the study will involve and how we will use the data you provide.
- The contact details for the central APRICOT study team are provided on the last page of this leaflet

If you have any questions about the study please contact:

Principal Investigator: {Insert local details}

Research Nurse: {Insert local details}

Please take sufficient time to read this information sheet carefully and talk to others, including your doctor and family, about the study if you wish.

Background to the trial

PPP is a relatively rare type of psoriasis that appears on the palms of hands and the soles of feet. The skin develops fluid filled blisters which usually fill with a small amount of sterile pus, turn brown, then scaly. There is no cure for PPP and the current treatments we have are of limited or no benefit, so there is a real need for something better.

Recent genetic research has shown that pustular forms of psoriasis may be caused, at least in part, by excessive production of a particular “messenger” protein (or cytokine) called interleukin-1 (IL-1). This protein, along with a number of related proteins, leads to the inflammation and pus formation that occurs in PPP.

Anakinra (brand name, Kineret) belongs to a group of drugs known as ‘human interleukin 1 receptor antagonists’. These drugs are sometimes referred to as IL-1 antagonists or IL-1Ra. They work by reducing the activity of IL-1 and so this might make them a potential new specific treatment option for PPP. In fact, small initial studies have reported these medications to be helpful in a small number of patients with pustular psoriasis.

Part 1: The Trial – what it involves

What is the purpose and design of the study?

The short name of the trial is APRICOT (Anakinra for Pustular psoriasis: Response In a Controlled Trial).

The purpose of this study is to determine whether 8 weeks of anakinra injections are an effective treatment for PPP.

We have chosen anakinra because it has been shown to have beneficial effects in early studies of patients with pustular psoriasis, it has a good safety profile, and it is already licensed for use in other inflammatory conditions (for example rheumatoid arthritis).

The study is designed as a randomised, double blind, placebo-controlled clinical trial. **Randomised** means that you will be randomly allocated (ie: by chance) to receive daily injections of either anakinra or placebo (dummy) treatment over an 8 week period. A computer programme will be used to perform this allocation of treatment so that it is fair and so that the best comparison can be made between the two groups.

Double blind means that neither you nor your doctor or nurse will know whether you are receiving the active drug (anakinra) or placebo until the study is completed at all sites and for all patients. The anakinra and placebo are packaged in identical syringes, with the same information. The placebo looks like the active medicine but contains no active ingredient. All participants will be assessed and monitored in exactly the same way. However, in an emergency, your doctor can find out which treatment you are receiving if knowing which treatment you are receiving is necessary for your safe care.

Why have I been invited?

You have been invited to take part in APRICOT because your doctor has diagnosed you with PPP requiring treatment that has not responded to topical therapies (creams and lotions).

Do I have to take part?

No. It is up to you to decide whether or not to take part. Please read this information sheet carefully and ask the study team any questions you might have to help inform your decision. Your decision will not affect the standard of care nor the treatment that you receive in any way.

What will happen to me if I take part? What will I have to do?

If you decide to take part, you will be asked to sign a consent form. The trial schedule is then as follows:

(i) Screening (one visit)

We first need to make sure it is safe for you to take part and to confirm that you are eligible. To do this we will invite you to a screening visit at which you will provide a detailed medical history, have a physical examination, have clinical assessments of your skin and provide blood/urine samples.

Anakinra is a biologic therapy; a type of drug that works by targeting the immune system, decreasing immune reactions to reduce disease symptoms but also making patients more prone to infection. A particular focus of screening is therefore to carefully check that taking a biologic is safe for you.

You will also have an x-ray of your chest if this is indicated based on clinical examination and/or if you haven't had one done in the last 12 months. The results of these tests and clinical information will be used to confirm if you're suitable for the trial. Many of these assessments are used in the routine care of patients with PPP so should be familiar to you.

If you are currently taking medication for your psoriasis you will be asked to stop it 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 a biologic such as adalimumab (this is the longest) or as short as 2 weeks if you are just using creams and/or ointments. You will be monitored to make sure your skin doesn't deteriorate too much in the run up to starting the trial medication and that it is still safe for you to participate.

(ii) Baseline assessment (one visit*)

If screening was successful you will begin the trial phase and attend clinic for a baseline visit. At this appointment we will repeat the clinical examination and blood tests to make sure nothing has changed and will assess your skin to accurately record your baseline skin scores.

*If your screening blood tests were more than one month before this baseline visit you will be asked to come in a bit earlier for a blood test. If possible the trial team will just move the scheduled baseline blood test earlier in the day of your baseline visit so won't require a separate visit, but if this isn't convenient you will have to come in for another visit (or go to your GP) up to four weeks beforehand to have an additional set of bloods taken. This will allow us to look at some recent results before you start treatment to make sure your participation is safe.

At some hospitals the baseline visit will include having photographs taken of your hands and feet.

We will take some blood samples for our genetic and other investigations of inflammation and immune function (up to 33ml, the same as about 7 teaspoons of blood) and will also ask you to complete a set of questionnaires, mainly looking at how your PPP affects your quality of life. Please try to complete these as accurately and honestly as you can.

At the baseline visit you will start treatment and receive your first injection. The clinical research 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 for the 8 week treatment period. Please don't worry about this. Many people take daily injections (e.g. diabetics needing daily insulin) and you will soon get used to it. The trial team will provide you with enough injections for 4 weeks and will set you up for the daily text message reminder service or give you a diary card.

You will also be given a patient information card in case of an emergency. Please carry this with you at all times. At the baseline visit you may also have the option of providing a 2mm skin microbiopsy sample (under local anaesthetic) and/or a hair pluck sample (see table below for more details).

(iii) Treatment Period over 8 weeks (3 visits)

You will self administer (at home) daily injections under the skin for 8 weeks. Your research nurse will provide you with all the necessary supplies, support and instructions, including a sharps bin which can be returned to your GP or local

pharmacy (depending on local guidance) or to the study team when full. Every day you will either receive a text reminder or be asked to fill out your diary card as a record of your injections. **If you miss an injection do not take a double dose, but let your research nurse or doctor know as soon as possible.** Please return all empty packaging and unused syringes at every clinic visit.

You will be seen in the outpatient clinic 3 times over the 8 week treatment period after the baseline visit; at week 1, 4, and 8. We estimate that these visits will take approximately 2 hours each, and will consist of an assessment of your symptoms, completing questionnaires about how your skin affects your daily life and providing urine and blood samples for routine monitoring of the effects of the study medication.

An independent assessor will look at your hands and feet before you see your study doctor at each visit. **It is important you do not talk to the assessor about any other aspects of your involvement in the trial or how you've been getting on. This ensures that the assessments are performed independently (i.e. blind) from any knowledge about problems or benefits you may have noticed yourself so we are confident of the finding in the trial.** The independent assessor may not talk to you beyond a couple of set phrases. This is APRICOT trial procedure and they are not meaning to be rude! Please **just show them your hands and feet** so they can carry out the trial assessments (counting pustules and determining the severity of your skin disease).

Additional blood samples (8ml the same as about 2 teaspoons) will be taken for further laboratory analysis of inflammation and immune function, at visit 2 and 4 (week 1 and week 8). At selected sites only, you will also have another set of photographs of your hands and feet taken at your week 8 visit. During the treatment period there is also the option of providing another microbiopsy sample and some more hair pluck samples (see table below for more details).

Whilst taking the trial medication you may continue taking other medication as directed by your doctor or GP for other conditions. However, you must not take the following:

- Medications which may help your PPP: topical treatments (apart from moisturisers), systemic retinoids, ciclosporin, other immunosuppressants, methotrexate, biologic psoriasis treatments (e.g: adalimumab or ustekinumab)
- Oral or injectable forms of glucocorticoids (steroids)

The trial team will ask for details of all medication at each visit. It is important you let your study team know if you feel unwell, need to visit a Doctor, need new or have any changes to your existing medication, or are worried about any aspect of your involvement at any time. Don't wait for your next visit. Use the contact details in this leaflet and that the team provide to you to get in touch immediately.

(iv) Follow up (2 visits)

Once you have completed the 8 week course of treatment, you will be seen in the outpatient clinic 4 weeks later for a follow up visit (week 12). At this visit you will have similar assessments to those conducted during the Treatment Period, including a last set of research blood tests (8ml, the same as about 2 teaspoons) and will be asked to complete a final questionnaire regarding overall acceptability of anakinra as a treatment for PPP. At the end of the study your study Doctor will advise you about future treatment and you will return to routine clinic care.

90 days post your last dose of trial medication you will have a final follow up visit. At this visit you will be asked if there have been any changes or additions in your concomitant medication and if you've experienced any illnesses or side effects since your last visit. This visit may be conducted by phone if you are not regularly attending clinic.

Table Summarising study assessments and timing

Tests	Study Visit (Screening to 12 weeks)	Purpose
Medical History	Screening	To find out about past and present disease and medications
Chest x-ray (unless performed within last 12 months)	Screening	To check your lungs as part of eligibility screening
Routine Blood tests and Urine sample	Screening, Baseline (and up to 4 weeks beforehand if applicable), Week 1, 4, 8, 12	Screening bloods will be used to exclude the presence of infections (Tuberculosis, HIV, Hepatitis B and C), as part of routine care. Routine safety monitoring will also include urine analysis, full blood count and liver function tests, as well as markers for disease monitoring. This is the same sort of monitoring that is undertaken for patients with PPP.
Physical Examination	Screening, Baseline, Week 1, 4, 8, 12	Clinical assessment to ensure eligibility and safety
Assessment of hands and feet	Screening, Baseline, Week 1, 4, 8, 12	To identify any changes in PPP symptoms (e.g. fresh pustule count) during the trial - carried out by an independent assessor
Patient Questionnaires	Screening, Baseline, Week 1, 4, 8, 12	This provides information about your daily activities and how your skin condition affects your daily living (x4)
Monitor study medication	Week 1, 4, 8	You will be asked to return any unused syringes and empty packaging at every clinic visit, and will be asked how you are managing with your injections. In addition, automated daily text messages will be sent to remind you to take your medication, or you will complete a diary card.

Monitor other medication and side effects	Baseline, Week 1, 4, 8, 12	Check for any side effects and collect information about other medications you may be taking. If something happens between study visits that means you see a doctor or need any new medication please call your study team immediately.
Blood tests for genetic/functional investigations	Screening, Baseline, Week 1, 8, 12	To investigate genetic and immune function factors that might influence response to anakinra and PPP symptoms.
Medical Photographs of hands and feet (selected sites only)	Baseline, Week 1 & 8	To help document any changes in your PPP symptoms
Skin microbiopsy (optional)	Baseline & week 1	A 2mm microbiopsy sample from pustule free skin on the edge of your palm, taken under local anaesthetic. To investigate the cells and proteins in the skin and to learn more about the relationship between each person's specific genes and their response to anakinra.
Hair Plucks (optional)	Baseline, Week 1, 8, 12	To investigate the cells and proteins from hair samples, to learn more about the relationship between each person's specific genes and their response to anakinra.

Which moisturisers can I use during the trial? Can I use anything else?

You can continue to use any moisturiser during the trial.

However, you will be asked to stop all other topical treatments up to 2 weeks before your baseline visit and won't be able to use them throughout the trial period. The study team will confirm this with you at screening but this includes corticosteroids, vitamin D analogues, calcineurin inhibitors, retinoids, keratolytics, tar and urea.

If your PPP flares during the trial your study doctor may prescribe a 'rescue' treatment with a topical corticosteroid eg: betnovate, mometasone furoate (EloconTM) which you should use as instructed.

What are the alternative treatments?

You do not have to take part in this trial. Your study doctor can tell you about other treatment choices for your PPP. These alternatives may include treatments which are applied on top of the skin like ointments and creams with or without corticosteroids, Vitamin A preparations, photo therapies (UVB, PUVA), or systemic treatments (taken orally) such as retinoids or ciclosporin.

You may choose to:

- Continue to get regular care from your doctor
- Take part in another study
- Get no treatment at this time.

Talk with your study doctor about your choices.

Expenses and payments

You will be reimbursed for reasonable travel expenses during the course of the study.

What are the possible benefits of taking part?

There is the possibility that patients taking part in APRICOT will see benefits to their health including seeing a reduction in PPP symptoms. Although we cannot predict the outcomes of the trial, you will be monitored very closely by the clinical research team and will have access to a dedicated research nurse. Close monitoring and contact will allow the team to answer any questions or concerns you have relating to your care and well-being throughout the study.

Very little research has been done into this condition, so while your participation in this trial may not benefit you directly, it will provide invaluable new information about the feasibility, acceptability and effectiveness of anakinra in patients with PPP and might lead to significant improvements in treatment options for the future. We also hope that the data collected by this research will explain why and how people develop this condition, which may then lead to other new treatments.

What are the possible disadvantages and risks of taking part?

To take part in the trial you will need to attend 7 study visits and learn how to self administer the trial injections which may be time consuming. Your study team will endeavour to make your visits as streamlined as possible but we recommend you allow about 2hrs per study visit and set aside a regular time each day for the injection.

Anakinra is licensed as a daily injection so its disadvantages and risks are well documented. The main ones to consider, alongside general trial related risks, are below:

(i) Risks related to stopping your normal treatments for PPP

All participants will need to stop their normal treatments prior to the trial and will be limited to taking the trial medication (either active or placebo) as their only systemic (ie by mouth or injection) treatment for psoriasis for the duration of the trial. Moisturisers are allowed throughout study, and some topicals (called 'rescue' medication) if your study doctor feels this is necessary. You will be closely monitored all the time so that in the event of new symptoms and signs of PPP, assessment and treatment can be given promptly by specialists experienced in caring for patients with the condition.

(ii) Risks related to the trial treatments

This a randomised placebo controlled clinical trial, and so there is a 50:50 chance that you will be given dummy treatment as opposed to the active study drug (anakinra). The injections (whether active or placebo) may not help or may even

worsen your symptoms of PPP. Regardless of the medication being injected you may experience injection site reactions such as stinging and itching; these are usually minor and very rarely lead to withdrawal of treatment.

(iii) Possible side effects

Very common side effects (affecting more than 10% of patients) are injection site reactions and headaches. Injection site reactions usually appear a few days or weeks after the injection as a rash or red inflamed area around the site of injection but can also be more immediate with a stinging or burning sensation at the time of injecting. The research nurses will explain what to expect and will tell you what to do to minimise discomfort and treat any reactions that you might experience – for example using a cold pack and antihistamine creams.

Common side effects (affecting 1 - 10% of patients) include upper respiratory tract (throat or chest) infections, and a decrease in neutrophil & platelet counts.

Uncommon side effects (affecting 0.1 – 1% of patients) of anakinra therapy are allergic reactions, changes in liver function, and rash.

Your treatment will be monitored closely through regular clinical assessments and blood testing so that any infections or side effects can be detected and treated promptly, and/or the trial treatment discontinued. Please don't hesitate to talk to your study team if you are worried about any of the above at any point during the trial.

(iv) Risks to the unborn child.

Anakinra may present unknown risks to an unborn child; therefore women who are pregnant or breast-feeding will be excluded from this study.

Women taking part in APRICOT will be advised to carefully follow adequate contraception guidelines during the treatment period **and for up to 14 weeks after the last dose of study drug**. If you could become pregnant, you will be asked to have a pregnancy test before taking part and at the end of the study. You should be using reliable forms of contraception during the study, e.g. oral contraceptive and condom, intra-uterine device (IUD) and condom, diaphragm with spermicide and condom. If you do become pregnant during the course of the study, we would ask that you tell your research doctor immediately so they can decide on appropriate action. We would discuss referral for specialist counselling on the possible risks to your unborn baby and arrangements will be offered to monitor the health of both yourself and your unborn baby.

It is unknown if anakinra will effect sperm or semen and therefore it is advised that men taking part in APRICOT do not father a child during the trial period without discussing the risks with your doctor. Male subjects will need to use adequate contraception during the period of treatment dosing **and for up to 14 weeks after the last dose of study drug**. If your partner might become pregnant you must use reliable forms of contraception e.g. oral contraceptive and condom, intra-uterine

device (IUD) and condom, diaphragm with spermicide and condom. If your partner becomes pregnant while you are taking study medication, or within 6 months of stopping treatment, you should inform your study doctor immediately. As the risk to your partner and baby is unknown, it is desirable for your partner to agree to medical supervision during her pregnancy and for the baby after it is born.

(v) Breast feeding

Participants must not breast feed during the period of study medication and **up to 14 weeks after the last dose of study drug.**

(vi) 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 the discomfort all samples, both for clinical monitoring and the genetic/immune function tests, will be taken at the same time by a clinical professional trained and experienced in taking blood from patients.

(vii) Risks associated with having a skin microbiopsy

Skin microbiopsy is a routine investigation performed within the dermatology department and our experienced staff will take all safety measures to reduce the risk of any complications from the procedure. If you choose to provide skin microbiopsy samples there is a small risk of possible bleeding at the site of the sample, bruising around the site, and infection of the skin where the sample has been taken. In some cases this may require treatment with antibiotics. A 2mm microbiopsy is taken under local anaesthetic and may require a stitch, although for such a small sample a stitch is usually not necessary. The dressing/plaster will need to be kept dry initially to make sure it stays in place but healing should be straightforward. You may have a small scar at the site of the skin sample.

(viii) Live vaccines

Participants should not have live vaccines during the period of treatment dosing and for up to 3 months after the last dose of study drug.

(ix) Exposure to radiation

All participants will undergo a single chest x-ray at screening visit if this has not been done in the previous 12 months. Experts on ionising radiation have been consulted and have confirmed that exposure to these x-rays carry a negligible risk – a dose (0.1 mSv) similar to that which people are exposed to naturally over the course of 10 days.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time and stop taking the study treatment without having to give a reason. This will not affect your medical care in any way. Your Dermatologist will explain your current condition and advise you on all the available next options.

The main purpose of the study is to find out how many participants on the active treatment, compared to those receiving placebo, have a reduction in their symptoms. For this reason, all samples and clinical information that we have obtained up until the point of withdrawal will continue to be used. Even if you are no longer taking the trial medication we would also very much like to continue to collect clinical data and mechanistic samples from you for some or all of the remaining scheduled trial visits, if you give permission. For safety reasons you will be asked to attend at week 8 and a follow up visit 90 days after your last dose even if you decide to withdraw.

If you would like to withdraw from the trial your trial doctor will make arrangements for your care to be continued in the routine clinical setting.

What happens at the end of the trial?

At the end of the trial your study doctor will assess your symptoms, discuss the treatment options and prescribe any appropriate further treatment.

Part 2: Further trial information

What if new information becomes available?

If new information about anakinra becomes available during the trial, your study doctor will tell you about it and discuss with you what to do next. If you decide to withdraw, you and your study team will decide upon your future care. If you decide to continue in the study you will be asked to sign an updated consent form.

To protect patient safety, an independent committee of experts will review the results of the APRICOT study at regular intervals during the trial, as well as information from other relevant trials. This means that if information emerges during the trial period suggesting that, for example, subjects receiving anakinra have unfavourable outcomes, then the trial may be stopped early or adapted. Your local study team will keep you informed.

Will my taking part in this study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. When you consent to take part in the trial you will be assigned an anonymised patient identification number (PIN). Your data and samples will be identified with this PIN number and only the Chief Investigator and approved delegated members of the study team will know which anonymised number relates

to you. . All those involved in the study will have a strict duty of confidentiality to you as a research participant and towards your data.

By consenting to take part you are agreeing that, in the event of an inspection or audit by the sponsor or Regulatory Authorities, authorised people may have access to your medical records to check the trial is being conducted properly.

Involvement of the General Practitioner/ Family doctor (GP)

With your consent, we will notify your GP about your involvement in the study. Your study doctor will also keep them informed about any changes in your condition during the course of the study, in line with current medical practice. If you have private medical insurance, you should inform your insurer that you are considering taking part in this study.

What will happen to my data?

Trial data will be stored on an online system maintained by the King's Clinical Trial Unit and hosted on a dedicated secure server within King's College London. Only authorised trial personnel will have password restricted access to the system. All data will be handled, computerised and stored in accordance with the Data Protection Act 1998.

Data relating to your samples will be held on a secure, confidential database for the purposes of this study, to which only the Chief Investigator and approved delegated members of the study team will have access. The database may be one developed and maintained by Guy's and St Thomas' NHS Foundation Trust, held on a secure server behind the NHS Trust firewall, known as CAPTURE. Identifiable information about you (eg name, date of birth and NHS number) entered on this database will only be accessible to the Chief Investigator and approved delegated members of the study team. By consenting to take part you are agreeing that, in the event of an inspection or audit by the sponsor or Regulatory Authorities, authorised staff and CAPTURE administrators will also have access to your identifiable information and study data.

Photographs will be stored on a separate NHS database locally and at the central site.

What will happen to any samples I give?

Blood taken for genetic and immune function analysis will be processed in your local laboratory before being sent for storage at the central storage facility, part of Dr Francesca Capon's lab at King's College London. All samples will be stored securely in accordance with the Human Tissue Act and national and local research governance guidelines.

Experimental analyses of the samples will be undertaken by the Chief Investigator's laboratory or designated investigators within the UK or abroad. These might include

commercial laboratories and/or external collaborators who have particular expertise in this field of research.

As part of the process of monitoring the safety of the treatment you receive, you will also be asked to give clinical blood samples at every study visit. These samples will not be stored, but will be processed and analysed by the hospital's clinical laboratory (as per routine blood tests). The results will be stored on the hospital computer system and recorded in the study documents, and will be reviewed by the doctor who is looking after you.

Will any genetic tests be done?

Yes. Understanding PPP is an important component of this study. Accordingly, some blood samples will be processed for genetic analysis in order to study genetic variation and its relationship to susceptibility to disease. We hope that this will enable us to make patient specific treatment choices in the future and help us to predict which patients are most likely to develop PPP.

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 pustular psoriasis. We may also want to contact you again for further information and/or samples. You will not be contacted with results from any tests performed on these anonymised samples.

What will happen to the results of the research study?

The results of the study will be collected by the Chief Investigator and the APRICOT study team. Their intention is to present the findings at dermatology meetings and publish the results in medical journals to circulate as widely as possible information about the best ways to treat individuals with PPP. This will take at least 4 years from the beginning of the study. When the results are published we will be happy to inform you on the specific treatment arm that you received and the overall results of the trial. No individual patient will be identified in any report or publication arising from this study.

Who is organising and funding the research?

This research is funded by a grant awarded to the Chief Investigator, Professor Catherine Smith, by the National Institute for Health Research as part of its Efficacy and Mechanism Evaluation Programme. The study is being sponsored by the Guy's and St Thomas' NHS Foundation Trust. The APRICOT study was conceived by the APRICOT trial steering committee and is not a drug company sponsored clinical trial. The pharmaceutical company who make anakinra (SOBI) have agreed to provide the drug free of charge.

Who has reviewed the trial?

All research in the NHS is reviewed in detail by an independent group of people called a Research Ethics Committee, with the specific objective to protect your safety, rights, wellbeing and dignity. The APRICOT study has been reviewed and given a favourable opinion by the London Dulwich Research Ethics Committee.

Advice has been sought from patients that have worked with the dermatology team at Guy's and St Thomas' NHS Foundation Trust, and a patient representative has also been invited to join the Trial Steering Committee.

The Research and Development Department of Guy's and St Thomas' NHS Foundation Trust have also examined all study documents independently to confirm that the study is feasible and that it will be conducted by clinical teams who have the expertise and appropriate facilities to carry out such as study. They have also received independent reviews by statisticians experienced in clinical trial design and experts in rheumatoid arthritis.

What if there is a problem?

(i) Questions and Concerns

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Alternatively, you can contact the Chief Investigator, Prof Catherine Smith. Contact details are provided on the final page of this information leaflet.

(ii) Complaints

If you have a complaint, you should talk to the research team who will do their best to answer your questions. If you remain unhappy, you can make a formal complaint through the NHS complaints procedure. Details can be obtained through the Patient Advisory Liaison Service (PALS) on XXXXXXXXXX, address: XXXXXXXXXXXXXXXX. This study is insured by Guy's & St Thomas' NHS Foundation Trust under the Clinical Negligence Scheme for trials.

(iii) Harm

All trial staff will be fully trained and certified before taking part in any trial related activities, and every care will be taken during the trial. In the unlikely event that you are harmed during the research and this is due to negligence then you may have grounds for legal action for compensation against that NHS Trust but you may have to pay your legal costs. The normal NHS complaints mechanisms are available to you.

Further information and contact details

If you have any questions about the study at any time, please feel free to contact your consultant dermatologist, local APRICOT study team, or the Chief Investigator and central trial office via the contact details below.

CONTACT DETAILS	
Principal Investigator Research Nurse (Insert Local Research Name & Address) Tel : (Insert Local number)	Chief Investigator: Professor Catherine Smith Professor of Dermatology & Therapeutics Consultant Dermatologist St John's Institute of Dermatology Guy's Hospital, London Tel: 0207 188 7188
APRICOT Study Team Skin Therapy Research Unit 9th Floor, Tower Wing, Guys Hospital, London, SE1 9RT www.apricot-trial.com Trial Manager: Rosemary Wilson rosemary.wilson@gstt.nhs.uk APRICOT Research Nurse: dermatologytrials@gstt.nhs.uk Tel: 07717 697435 (during working hours) In emergencies please contact your trial doctor or local emergency services	

