



Treat



The TREATment of severe Atopic eczema Trial

93 patients recruited

All 13 site now open

9 patients to go!

Meet the Team at Our Lady's Hospital, Dublin

Recruitment Progress

Site	No. Recruited
Guy's & St Thomas' Hospital	41
Royal Hospital for Children, Glasgow	9
Royal Victoria Hospital, Belfast	8
Nottingham University Hospitals	7
Oxford University Hospitals	2
University Hospitals Coventry and Warwickshire	11
Poole Hospital	2
Sheffield Children's Hospital	5
Ninewells Hospital, Dundee	1
Whittington Hospital	1
Bristol Royal Hospital for Children	2
Our Lady's Children's Hospital, Dublin	4
Total	93



Prof. Alan Irvine writes: "In this era of exciting, but costly new treatments for atopic dermatitis, there is a real need to evaluate and develop an evidence base for existing conventional oral medicines which cost a fraction of new treatments and which still have an important role in the AD therapeutic armamentarium"

Well done to the team in recruiting 4 patients within 4 months!



Visit us at www.treat-trial.org.uk



Meet the Team at Birmingham Children's Hospital



The Birmingham site is the final site to open to recruitment for TREAT.



Recruitment Incentive

Congratulations to Dr Jane Ravenscroft and her team at Nottingham who recruited the 80th TREAT participant. They were gifted with a hamper from the Chief Investigator. **The next hampers will go to the sites who randomise the 100th, 101st and 102nd patient. Keep the patients coming!**



Trial Extension

You will all be pleased to know that the EME Board have approved a 15 month trial extension.

In order to help us achieve the original recruitment target of 102, the recruitment end date has also been extended to the **31st January 2019.**



Research Samples

The research samples are currently stored at site and not to be transported to external laboratories until the end of the trial, unless otherwise informed. In order to ensure a robust sample tracking and monitoring process is in place, please send copies of all sample logs to the CTRC.



Data Queries

The trial team would like to take this opportunity to thank you for completing the data queries in a timely manner. We appreciate that this is time consuming and thank you for your continued support. Please keep up the good work.



Please ensure that all unused trial treatment is collected at each site.



Week 48

Please note that safety bloods should not be collected for trial purposes at the **week 48** visit as per protocol. If safety bloods are required for clinical reasons, please ensure that the results are not recorded on the CRFs.



CRF reconciliation

As a number of participants (36) have now completed the trial, the Data Manager will be contacting sites to ensure that all CRFs have been received and copies have been retained.



Protocol Amendment

We have clarified the co-primary outcome definition that 'significant re-flare' means that either the o-SCORAD returns to baseline level or the local clinician made the decision to re-start systemic therapy. This will then align better with clinical practice. Clarification on how sites should collect data for patients that discontinue from trial treatment has also been included as well as additional measures to improve the completeness data for the health resource use collected in the patient diary.



Severity Assessments

Please ensure that the severity assessments are carried out by the **trained blinded assessor**. Please reschedule the patients visit where possible to avoid a unblinded assessment. Please also remember that blinded assessments should continue even when the participant has stopped trial treatment.



Consent/assent forms

Please ensure forms are sent to the CTU **within 7 days** of the screening visit as per protocol. This can be sent via fax/post or secure NHS.net email.



Patient Diary

Health Economic Questions - resource use

The health resource questions are located at the back of the diary and include questions as to whether a healthcare professional was seen, whether antibiotic creams or tablets were prescribed for a skin infection and whether any time off nursery or school was required.

Health Economic data is an important outcome measure of the trial and the low completion rate could jeopardise the integrity of the trial data.

Please could you ensure the following measures are put in place:

- ⇒ Provide clear verbal instructions on how to complete the diary to parents.
- ⇒ Show the patient the last two pages of the diary to highlight the importance of completing the health economic section.
- ⇒ Thoroughly check through the diary once returned, whilst the patient is still present.
- ⇒ Assist patients' to complete missed questions during their visit and ensure the response box "no" has been ticked where no visits/medication or time off work/school have been needed.

POEM (collected via patient diary)

Please could you remind patients to record the dates in their diaries and also ensure that the dates have been recorded when reviewing the patient diary at their next visit.

For later visits, when the diaries are given in batches, please do not write the same date on the front of all the diaries. We suggest that you write the date of the visit on the first diary and also a no. '1/first'. Then '2/second' '3/third' for subsequent diaries. This will help us make an assumption on when the patient completed the diary if the dates are missed in error.



thank you!

Thank you for all your hard work with recruitment! If you are experiencing any issues with recruitment or have any queries please do not hesitate to



Contacts:

Trial Co-ordinator Farhiya (Fee) Ashoor
Treat.Trial@liverpool.ac.uk

CI - Carsten Flohr
carsten.flohr@kcl.ac.uk