

Update August 2017

Dear Friends,

Since I last wrote to you, myself, Dr Renuka Dias and Dr Ben Wright, and the Clinical Trials Unit team in Birmingham, have been working hard to get all the documents ready for the European clinical trial. We have been doing further work on the study protocol. This is the document that everyone has to follow, so that people participate under the same rules as everyone else. One issue is trying to balance the number of times we ask participants to visit Birmingham, with the distances people may have to travel. We are looking at several visits in the first 6 months, to check for safety; then visits twice a year. We hope to get support to reimburse at least some travel and accommodation costs for families taking part.

Secondly, Shazia Ahmed and Rebecca Storey, who are clinical trial coordinators, have been working on the case report forms. These record all study related information as a paper copy; which then gets converted into an electronic database so that the study nurse can input outcome and safety data electronically. This has to be standardised so that information is entered to the same standards whether in UK, Spain, France or Poland. We hope to complete this by the end of August, so that the electronic database can be built.

Thirdly, we have been trying to source the study medicine and matching placebo, at an affordable price. We budgeted for £150,000, based on a quote we had from a pharmacy in London; however due to sourcing and stability issues, quotes are now coming in at £500,000 and upwards. We are working with the study funders and different manufacturers to get this cost down. However this has been a headache and we hope to make a final decision by the time of our investigator meeting at the end of August. The issue of getting a manufacturer to do all the relevant testing of the medicine, and supply with matched placebo in identical containers, has delayed the start of the study, and we now have to plan for a date for first participant recruitment of 1st February 2018. I know this will be a disappointment to you, but the pharmacy manufacture issue is one that we had not anticipated in our planning for this trial.

We have a trial management group meeting on 30th August, and I hope after that, I will be able to tell you of some better progress towards starting this study

I hope you all get some time to relax over the summer, even though the weather is a bit rainy, at least here in Birmingham!

With best wishes

Tim Barrett