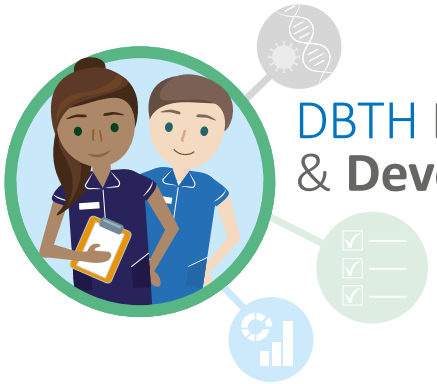

DBTH **Research** & **Development**

NHS
Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Newsletter
Spring 2021

This edition focuses on the studies working within the **Rheumatology department**

The Rheumatology department has been very active in research with a wide range of research portfolio from observational studies to highly intensive clinical trials. The past year with the Covid-19 pandemic felt like putting the department through a big stress test, not just from routine clinical work, but also our research activity.

The three main challenges we faced were:

Staffing

Redeployment to help manage Covid patients led to significantly reduced staffing levels which impacted on the ability to continue with our ongoing research studies.

Lack of clinical space

This affected research visits as many clinical areas (namely outpatients and day units) were closed in the initial phase of the pandemic.

Patient safety

There was concern that patients would avoid coming to hospital due to fear of contracting Covid-19 and patients might be out of medications (particularly in clinical trials) as research visits may not occur. This may result in deterioration of patient's clinical status, which was our main concern.

There had been many discussions and communications with the sponsors of research studies, research team and department to ensure patient's wellbeing and safety. Even though many research studies were suspended, clinical trials were supported to continue and contingency plans were made to ensure that patients did not run out of medication.

Through great teamwork, we have shown our resilience and came through the stress test (of the first phase of the pandemic) with flying colours. Since last summer, we have restarted research activity gradually and also started new research studies including clinical trials. We are in the process of getting back to routine research activity.

I am really grateful to everyone involved for the excellent teamwork in getting us to where we are now and also to our patients for their patience with us during these challenging times. It has been a pleasure doing research in this Trust!

Dr Chee-Seng Yee PhD FRCP
Consultant Rheumatologist

Laura's story

A patient who participated in a recent research study at DBTH, shares her experience.

"My research journey started five years ago. I feel blessed to have been offered research as an option. The first few treatments were daunting but the Research Team are only a phone call away. We got into a rhythm so everything ran smoothly... until 2020.

"I was anxious about the threat of covid and the risks to me. Shielding at home with a teenager, made coming to my treatment more like a day out.
A nice cuppa with some friendly, supportive research staff lifted my spirits. I had no need to worry about anything. Hidden behind their masks the Research Team organized everything, I just needed to show up, give some details and offer a nice juicy vein.

"My time on this trial will come to an end. I hope to continue with other research opportunities in the future. I am grateful for this chance to give valuable information towards possible future treatments and better understanding of my disease."

Laura Mackenzie

TWINSS

✔ Open ✔ Recruiting 4 Recruited participants

This study evaluates the safety, efficacy, pharmacokinetics (PK) and pharmacodynamics (PD) of multiple doses of CFZ533 (iscalimab) in patients with Sjögren's Syndrome.

This is a double-blind, randomized, placebo-controlled, multicenter study of CFZ533 in 2 distinct populations (cohorts) of patients with Sjögren's Syndrome: 1) moderate-to-severe disease (systemic and symptomatic involvement) and; 2) low systemic involvement but high symptom burden.

Recruitment target 2. Two patients now awaiting first dose of study medication. Positive results in Phase 1 and 2 studies, expected to significantly help patients suffering with this illness. The study will take place over 1 year with a possible 2 year extension.

ABBVIE

✔ Open ✔ Recruiting

ABBVIE is a commercial clinical trial opening soon. It is a study looking into the use of UPADACITINIB in patients with Ankylosing Spondylitis (AS). The study has a target of 2. Treatment has shown extreme promise, and the medication has been recently approved for use in similar condition (non-radiographic AS) in the EU. We are expecting positive results from this option for our patients.

MEADOWS

✔ Open ✔ Recruiting

The Meadows study is a new study for patients with Systemic Lupus Erythematosus. The purpose of this clinical trial is to evaluate the safety and efficacy of Pfizer, IP PF-06700841 tablets. The study has a target of 2. Treatment relatively unknown, similar medications have shown promise.

RECLAIM

Open | Recruiting | 0 Recruited participants

The RECLAIM study provides research into effacity of CSL Behring, IP IgPro20 (Hizentra) subcut infusion in participants with Dermatomyocitis. The participants receive an innovative method for drug delivery, aimed at increasing independence for the patients as well as providing a new treatment option. The study has only just opened, so no patients have yet been recruited. The study has a target of 1 participant although there are currently four patients who could fit the requirements of the study. RECLAIM is a 1 year study, with a possible extension.

TULIP

Now closed to recruitment | 2 Recruited participants

This study evaluates the safety and efficacy of two doses of Anifrolumab in adult patients with Active Systemic Lupus Erythematosus.

This is a double-blind, randomized, placebo-controlled, multicenter study at Stage 3. The TULIP study opened at site in 2015 and has therefore been giving Lupus patients opportunities to have treatments that aren't yet available on the NHS for around five years.

The Trust recruited the first European patient. In all, two patients were recruited and one has completed. Both patients from the TULIP study went on to the TULIP LTE (long term extension).

BRAVE

Open | Recruiting | 2 Recruited participants

The BRAVE study provides research into effacity of the baricitinib drug in participants with systemic lupus erythematosus (SLE). Eli Lilly, IP Baricitinib tablets, two patients have been recruited, which means the target has been reached for this study. Both participants have stated they have had positive experiences of research. They've not only enjoyed the benefits of a different treatment option, but also the ability to regularly touch base with an expert consultant and the research team. The study has a three year extention.

Compact

Now closed to recruitment | 16 Recruited participants

Compact study is a multicenter, prospective, observational cohort study to evaluate the real-world safety and effectiveness of Erelzi™, an etanercept biosimilar.

The Trust has recruited 16 patients onto the study who will be followed up for two years.

Rheumatology Psoriatic Arthritis Register (BSR-PsA)

Open | Recruiting | 13 Recruited participants

Dr Yee is actively recruiting to the British Society for Rheumatology Psoriatic Arthritis Register (BSR-PsA) study, sponsored by the University of Aberdeen.

The study evaluates the long-term course of PsA and patients are followed-up regularly, comprising patient and treatment characteristics, clinical parameters, patient-defined benefit, quality of life and serious adverse events. The study, in the first instance will run for five years. We are currently ahead of our recruitment target.

PROSPIRIT

Open | Recruiting | 7 Recruited participants

This study evaluates the use of new DMARD therapies **in** patients with Psoriatic Arthritis.

This is a commercial clinical trial for Eli Lilly. It has a two year follow up for patients. We have recruited seven of the target of 12 patients and are on track to hit or exceed our target.

RABEREAL

Now closed to recruitment | 6 Recruited participants

This is a commercial clinical trial for Eli Lilly for patients with Rheumatoid Arthritis starting new DMARD therapies.

The Trust has recruited six patients onto the study who will be followed up for three years.

SERENA

Now closed to recruitment | 8 Recruited participants

The Serena study is a commercial clinical trial for Novartis focusing on a mixture of Rheumatological Illnesses. The Trust has recruited eight patients onto the study and will be followed up for four years.

If you would like to become involved in either leading a new trial or supporting an existing one, then please do get in touch.

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