

## Dexamethasone in patients with CELLulitis

### The DEXACELL Trial

#### Diabetes Information Sheet

**You are reading this because you have diabetes and are considering/taking part in The DEXACELL Trial, which aims to investigate whether the addition of dexamethasone (a steroid) reduces pain and other important patient outcomes in people with cellulitis. This diabetes information sheet outlines some important information about your diabetes and taking part in DEXACELL, and should be read in addition to the main study Participant Information Sheet.**

#### **Why does my diabetes matter when I have infections like cellulitis?**

People with diabetes often have higher blood sugars than other people and use medications such as metformin and insulin to control this. We know that when people get infections like cellulitis this can alter the level of blood sugar and also mean people need to change the amount of medication they take (usually increasing their requirement for drugs like insulin). Your doctor should discuss this with you. There are established 'sick day rules' which describe how to manage your diabetes during infection and illness which are attached to this information sheet and are available here: (<https://www.diabetes.org.uk/guide-to-diabetes/life-with-diabetes/illness>)

#### **Will entering the study have any effect on my diabetes and blood sugar management?**

In this study, we are providing half the participants a steroid (dexamethasone) and half will get a matched 'placebo' (a dummy pill that looks the same but contains no real medicine). Neither you or the doctors treating you will know whether the capsules you are taking are a placebo or if they contain steroid.

We know that steroids – in addition to illnesses like infection – can increase blood sugar measurements. We are therefore asking participants with diabetes to adhere closely to the sick day rules and keep a close eye on their blood sugar management during participation in this study. This would always be recommended for anyone with infection but as the doctors and teams treating you will not know whether you are taking the steroids it is more difficult to predict whether your blood sugars will be impacted by the medication in this study.

In line with diabetes UK guidance, we recommend checking blood sugars **every 4 hours** for those people who already check their blood sugars at home. If you don't normally need to check blood sugars at home, then you can ask your treating doctors if you should.

#### **How long will my blood sugars be abnormal for?**

Blood sugars can be variable during any infection until it resolves. This is likely to be for a couple of days and up to a week depending on the severity of the infection. The effect of the steroid we are giving in this study will only last for a few days and we would not expect blood sugars to be higher because of this after 3-4 days.

**Are the steroids likely to be harmful for my diabetes?**

We do not think the steroids will be harmful for your diabetes, but we know that people may have higher sugars and that for some people they might need to take more medication to treat their diabetes. However, this should not be a long-term effect and your diabetes management will return to normal after a few days when your infection is resolved and once you are not taking any medicines from the study.

**Why are we including patients with diabetes in this study?**

Patients with diabetes are at higher risk of getting infections like cellulitis and also are at higher risk of having complications. It is really important to find better treatments for cellulitis that work for everyone, not just for those without diabetes. Excluding patients with diabetes would make our study results harder to interpret and we would not be able to assume that dexamethasone would have the same effect on patients with diabetes who get cellulitis as it does on other patients without diabetes. Additionally, lots of recent trials of steroids have included patients with diabetes and there have been very few complications related to the steroids, while in many of these studies patients with diabetes benefitted. We think it is therefore important to include patients with diabetes in the study and we appreciate you taking the time to consider taking part.

**Taking part in this study is entirely voluntary and you can decide not to participate with no impact on your ongoing care or rights.**

**Contacts:**

If you would like to discuss the management of your diabetes whilst participating in DEXACELL please contact:

<insert site specific contact>