Patients Involved – Direct patient insight on Lupus

Introduction

A case report on Phase I patient involvement into study design through interviews where they share their views on the disease and the cutaneous symptoms. The information that patients shared helped the researchers to progress with designing a clinical trial.



Where in the process? – Phase I

When does it happen? – Phase I

Description of the case

In October 2015, two medical doctors and one scientist from GSK interviewed 5 female patients diagnosed with systemic lupus with cutaneous manifestations, or diagnosed with cutaneous lupus with skin symptoms only – four patients interviewed in Cambridge in the UK, and one patient interviewed over Skype.

The objective was to hear patients' views on their disease and on research because GSK is planning clinical trials of an investigational medicinal product in patients with cutaneous lupus.

Patients described a long history of the disease, and their general symptoms that impact on daily life, for example they become tired very soon, they have painful joints, cold feet and fingers, prolonged mouth ulcers, and they can feel isolated or have depression as they cannot always go outside or to work. With respect to the skin symptoms, the patients consistently reported that exposure to sunlight provokes or aggravates symptoms. This significantly limits outside activities, and they must put on sunscreen even several times a day. Skin lesions are itchy, can be thick, occur anywhere on the body including on the head or face, which can lead to social isolation. The patients indicated that they need several different treatments, all the time.

Type(s) of patient (advocates) involved

Patients with personal disease experience.

Expert patient / patient advocate with good expertise on disease, but little R&D experience.

EUPATI trainee with experience as a patient with the disease.

Doctors and scientists from GlaxoSmithKline (GSK) R&D, Immuno-Inflammation Therapy Area Unit.

Benefits of patient involvement

The patients reported a range of general symptoms that are associated with the cutaneous symptoms, and a range of treatments that they have to use every day. They said they would prefer a topical treatment so that they do not have to take another oral treatment. Ideally they would like the topical treatment to contain sunscreen so that they would not have to apply two creams. They would accept intravenous treatment if that meant they would generally be better. They

wish a new treatment would prevent or reduce the flares – ideally curing them. With respect to using UV provocation in a research clinical trial, they would think about it and may want reassurance that they would not develop a flare.

Challenges and barriers

The challenge was that the interviews were in Cambridge in the UK. The patients who responded had to consider travelling a considerable distance (from the Netherlands and Spain) to participate and were given the option to participate by telephone, those who decided to travel were provided with support in making arrangements. Nevertheless, it was a tiring activity for the patients. The interviews were structured with similar questions for each interview as far as possible. This may have seemed a little strict but it helped to ensure the areas that were discussed were standard across the patients. Following consent, four interviews were video recorded and all audio recorded. One interview required an interpreter.

Learnings

The patients were truly inspirational. They have overcome the challenges that the disease has imposed on their lives, and they wanted to help others by sharing their experience. It was apparent that the impact of the disease is broad. Patients would consider the potential effect of the clinical trial on their disease or their daily routine before considering participating in a trial, to avoid provoking a flare. They understand that research is required to find new treatments, and they also wish to share their experience to help others through patient organisations. The information that patients shared helped the researchers to progress with designing a clinical trial, which is planned to start during 2016.

Attachments

- Patients Involved Case Report: Direct patient insight on Lupus
  Size: 867,078 bytes, Format: .pdf
  An infographic describing Phase I patient involvement into study design through interviews where they share their views on the disease and symptoms to help the researchers to progress with designing a clinical trial.