

Clinical Trials in General Practice

By Dr Carol Sinnott, UCC

It's a Monday morning in my GP surgery. As I scan the list of appointments on my computer screen, I see it will be a busy day ahead: antenatal checks, medication reviews, diabetic examinations, lots of children, lots of older people.

My first patient is Ivy Byrne, a 62-year-old woman who is generally in good health but reports feeling excessively tired lately. I checked her over during her last visit a fortnight ago: everything looked fine. I ran some blood tests, and was reassured to find no sign of anaemia or infection or any problems with her liver or kidneys. However, one result was highlighted in red: her thyroid blood test. It's not alarming but it is *slightly* abnormal. It shows that Ivy's thyroid is borderline underactive, and is having to work extra hard to keep her body functioning at the level it should. Next question for me: what do I do with this result?

It's a tricky one: medical evidence tells us that once the thyroid gland hits a certain low level of activity (measured by a blood test) we should treat our patients with a medication called eltroxin. The treatment improves people's symptoms (such as tiredness) and reduces their risk of developing other problems, such as heart disease, later on.

If the blood test shows us that the thyroid is borderline underactive, as in Ivy's case, we do not know what to do. On the one hand, prescribing the same medication, eltroxin, may help Ivy feel less tired, and reduce her risk of heart disease. On the other hand, all medications have side effects, so we do not like to prescribe unless we know, with as much certainty as possible, that it is more likely to help our patient than harm them.

In the case of Ivy, I need to know what would happen to her if I treated her, but also what would happen if I did not treat her. If I had this information, I could confidently call Ivy in, discuss the options with her, and together we could choose a course of action to take.

The problem is that this essential medical information is available only from clinical trials. In a clinical trial, some people are treated with an active medication, others are treated with a placebo "sugar" tablet, and both groups are closely and carefully monitored to see which option is the safest and most beneficial for patients. Unfortunately for Ivy and me, good quality clinical trials on borderline underactive thyroid disease have not yet been performed.

So where does this leave me in my first consultation of the day? What do I tell Ivy? That her tiredness may be related to her thyroid, that there is a medication to help, but that I cannot tell her

for sure if it is safe or advisable to use this medication? Patients come to doctors for answers, not questions.

Luckily, there is a solution to this dilemma: a clinical trial ongoing in Ireland that is trying to answer this very question. The trial, known as TRUSTⁱ, is inviting people like Ivy who have borderline thyroid disease to participate. If she agrees, she will be allocated to the treatment group or the placebo group – but neither she nor I will know which, as the tablets appear the same. The research team organising the study will know what Ivy is taking, and as she is followed up for changes in her symptoms, the team will use this information to analyse the results and give us the answers we are looking for.

In return for her participation, Ivy will be closely monitored, and will have healthcare professionals (nurses and doctors) from the research team to contact if she develops any new symptoms or has any concerns. What's more, she will know that her participation is a generous contribution to emerging medical evidence. By getting involved with a clinical trial, Ivy would be joining a global community of people who are striving to improve medical knowledge and the provision of healthcare.

So back to my morning surgery, and the task at hand. In medicine, information is never static. New advances are made all the time, but patients' healthcare needs also change. We will never have all the answers straight to hand, just as I do not have all the answers for Ivy Byrne this morning. Clinical trials offer us a strong and safe mechanism for developing these answers. They are a reliable foundation of knowledge for me and my GP colleagues. This knowledge allows us to confidently discuss treatment options and implications with our patients. Thus, clinical trials ultimately enable shared decision-making and patient involvement in healthcare that is evidence-based, and safe.

ⁱ More information on the TRUST study (Thyroid hormone Replacement for Untreated older adults with Subclinical hypothyroidism; a randomised placebo-controlled Trial) can be found on www.trustthyroidtrial.com