

# Diary of a Clinical Trial Participant #1

Author Profile:

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# Diary of a clinical trial participant – Malaria Challenge Trial

## *Participant Details:*

*Female, 37 years old, married mother of two, working full time.*

This diary was provided to Research4Me by a person that participated in an early phase clinical trial, in the hope that sharing her experience might help others understand more about clinical trials.

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Please share this with others that you think might be interested to read about her experience.

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## Volunteering for a clinical trial

How do you pick which trial to volunteer for – there are so many trials and they are all so different. Some only want males (can't go on that one). I'm not too keen on being injected with a vaccine (don't ask me why) and they go for over three months – I'm too impatient for that. At least I pass the contraception requirements – my husband and myself have no desire for more children and have taken the necessary steps to ensure that I don't get pregnant again. I hear about a series of trials where you get injected with Malaria and then treated with the anti-malarial drug; they are comparing new drugs with the existing drugs. Sounds cool and with a short timeframe – only goes for 10 days – short and sweet. I talk about it with the husband – he is a bit worried that I will get sick with the Malaria, but says, sounds like fun – go for it.

## Reading the consent form

This consent form is so long, who writes these things? I will never remember all of this stuff (ie: what I can and cannot eat, no poppy seeds). This trial is a good one – I can still have coffee, but I have to give up on the alcohol for 10 days – probably not a bad idea to have a de-tox session and in effect I will get paid for de-toxing. The actual trial seems easy enough to understand - get malaria, get lots of needles to take blood to watch the malaria grow, maybe get sick (hopefully not), get treated with the current best available drug, leave, get paid.

## Screening Day (Tuesday)

I arrive at the Clinic fasting (I'm so hungry and with a full bladder for my urine sample). There is one question running through my mind – Am I normal and healthy enough to pass the screening requirements? I hope so. It's a bit scary – like taking an exam – will you pass, are you normal? I meet with the lovely doctor who goes through the consent form – it takes forever, but she never seems in a rush and answers all my questions. A nice lady takes my blood (doesn't even hurt) for analysis and they perform an ECG- to test your heart health, they put stickers on your chest, attach some wires and you lie still for about 5 minutes. The blood test will be used to check that I'm not pregnant, don't have HIV, Hepatitis B or C and many other things –I hope I don't have HIV – that would be bad.

### Passing screening

The project manager has rung, I have passed the screening, yippee – I'm healthy, normal and not pregnant. I have good blood, good heart and no unknown diseases (no HIV – relief). I'm to be the reserve participant, which means I'll turn up for the dosing, watch the other guy get injected with malaria, collect my \$150 and go home – nice work.

The project manager rings again – the other guy has pulled out; wonder why? It's just me who will be getting dosed with malaria tomorrow. I'm excited, anxious, curious and full of anticipation.

### The night before dosing

I'm having trouble getting to sleep – I'm so excited. That may sound really weird, but that's how I feel – this is like starting a new adventure, no-one quite knows what will happen. Maybe it's the scientist in me – this is like the coolest experiment ever and I'm the star.

### I'm In...

#### Day 0, Dosing Day (Wednesday)

I arrive at the Clinic about 8am, (full bladder again - they always want your urine these greedy people). Urine pregnancy screen comes back negative – relief – still not pregnant (one would hope not – I've had my two kids, I don't want any more). Turns out my blood serum pregnancy test has not arrived yet – so there is a bit of waiting for yet another confirmation that I am not pregnant – they really don't like pregnancy these Clinic people.

Finally, confirmation – I am not pregnant. People arrive from everywhere (one wants my blood, one wants my blood pressure and the other wants to give me malaria – The malaria lady has a very official looking esky and in that big box is a little tiny tube with my malaria. I think to myself, this is it – last chance to pull out – nah – let's go and have some fun – my own experiment. Canula goes in to my right arm, doesn't hurt as much as I thought it would and in goes a very small amount of a clear liquid filled with Malaria parasites. I lie around in the bed for about one hour, don't feel any different. All good, they say and I go to work for the rest of the day.

## Day 1 (Thursday)

It's the morning after the dose - No malaria yet - I feel fine, not sure what to expect. I go to the gym in the morning and then work. The project manager rings to check that I am ok - I feel really good, must be the lack of alcohol.

## Day 2 (Friday)

Same as yesterday, I feel fine - project manager rings again to check that I am ok - I still feel good, maybe malaria is good for you. I go to the gym and work.

## Day 3 and 4 (Saturday and Sunday)

I drop in to the Clinic for the first of my AM blood collections - they will be monitoring my malaria parasite growth by PCR (a very sensitive technique, so they will know when my malaria parasite counts are high enough to commence the drug treatment, this usually happens before people get sick).

I am going away for the weekend on a road trip with my girlfriend (we planned it 3 months ago). Only problem is that I am not allowed any alcohol – alcohol and malaria don't mix. Turn out all ok – we even go to three wineries and I am fine with not having any alcohol, my friend tells me what the different wines taste like and I buy a bottle to celebrate the end of the trial. I focus on eating all the lovely cheeses and fig jams. Actually, given that I am driving, it works out very well to be abstaining from drinking. We leave the third winery, drive into a small country town and I get pulled over by a RBT – thank god for my trial and my abstinence from drinking.

### Day 5 (Monday)

I now have to go to the Clinic twice a day in the morning and the evening for blood collections. It's so quick, I rest on the bed for 5 minutes, they take my blood pressure and take some blood. The Clinic nurses are really good with their needles – doesn't even hurt – a green ant bite hurts way more. I also get to leave each time with the famous Clinic muffins (there are 3 different varieties) and orange juice (free food – who can complain).

I pack my bag tonight for my overnight stay and leave it in the car - what if they call me in early because my malaria has grown quicker than expected? There are big decisions to be made in the packing - which PJ's should I wear, which DVD's should I pack, I down-load some new books to my kindle for reading during my overnight stay. I double-check that I have all of my recharging devices – I would hate my laptop or phone to run out of batteries during my overnight stay.



## Day 6 (Tuesday)

Same as yesterday, more blood test in the morning and evening. I actually feel really tired this morning (maybe it's my malaria – I am scheduled to start the drug tomorrow morning), blood gets taken (the needles still don't hurt), my vitals are fine, so I go to work - I feel better after the Clinic muffins :)

Project manager calls in the afternoon, still not enough malaria parasites in my blood, so no admission tomorrow. When will my PCR ever be positive, surely I can grow parasites? Project manager says no admission until Thursday morning (maybe). These human trials are always subject to variability. I have to ring the hubby and reschedule the kids school pick-ups and drops offs. It's kind of hard to schedule your life when you could get sick at any moment (or not). But, hey that's what normally happens in life, this is no different, we just carry on like normal and deal with the unexpected when it turns up. I go to bed every night expecting to wake up in the middle of the night with sweets/fever etc. But so far, nothing, not enough malaria parasites and I feel perfectly well. Maybe malaria is good for you (or maybe it is the fact that I have not had any alcohol for 8 days now).

## Day 7 (Wednesday)

Same as yesterday, more blood test in the morning and evening. I feel much better today. Project manager rings in the afternoon – my PCR has come back positive – yippee – I officially have enough malaria parasites to be treated (still feel 100% well, weird). I finish work and drop into the Clinic for my evening blood test and go home and re-pack my bag. I have decided to change the pyjamas that I have packed – I prefer the yellow 'wonder women' variety.

## Day 8 Drug Treatment Day (Thursday)

*6am, Thursday:* I wake up early and dress in my very comfy tracksuit pants - after all, I will be lying around all day watching movies, reading books. Fasting again, no breakfast or coffee (can't have coffee in the Clinic) and drive to the Clinic for my drug treatment. First things first – they want a breath test for alcohol – no worries there – I haven't had a drink for 8 days now. Then it's over to the clinic and yep you guessed it – they want more urine to prove that I have not had a miraculous conception in the last 8 days. I have a bit of stage fright this morning and can't provide the urine sample straight away (how embarrassing – what a time to fail to produce!) – so we decide to proceed with checking blood pressure and doing another ECG to make sure I still have a beating heart; I start drinking lots of water. The nurse puts the cannula in my left arm and they take some of my malaria filled blood (they will be taking blood every 6 hours for the next 36 hours) – one cannula needle is better than a needle every 6 hours. I grab the urine specimen jar and have much better success on the second go. We wait around for the results of the urine pregnancy test and drug screen – yep – still not pregnant and no drugs (I could have told them that – but these Clinic people need the evidence).

*8.30am, Thursday:* It's time for my first-dose of the anti-malarial drug, which has to be taken with food, so I get a lovely Clinic supplied breakfast and then take four small tablets with milk – no worries, I love milk. No changes at all after the first dose of the drug, I feel fine. Now, my job is to lie back and read books, watch DVD's and do whatever I wish for the next 24-36 hours. I decide to use the Wi-Fi and start writing various e-mails for work. I'll save the X-box and large screen television for later.

*9.30am, Thursday:* I am typing away at my e-mails and start to feel a headache come on; I figure it's probably due to not having my morning coffee and staring at my small laptop computer screen whilst lying on a bed (or maybe it's the stupid work e-mails). So, I turn off the lap-top and have a lie down. My headache gets much, much worse, I can't bear the light and even the smallest pin drop sound becomes painfully loud. I bury my head underneath a pillow and the Clinic staff grab me an eye mask, ear plugs and some panadol. They turn off all the lights and close the curtains around my bed. I fall blissfully asleep (thankfully).

*Midday, Thursday:* I wake up from my headache induced slumber feeling a lot, lot better. I text the husband to let him know all is ok. I feel really good and very hungry. I have some really tasty chicken curry for lunch and a decaffeinated coffee. I feel really good after lunch. The project manager tells me that my malaria parasite count is the highest they have seen for some time – I feel so proud. What a super, duper malaria growing machine I am! They also tell me that some people feel quite sick as the malaria parasites are being killed by the drugs and that aversion to light (ie: photophobia) is also common.

*1.15pm, Thursday:* I am watching the most recent James bond movie 'Skyfall' when my malaria-killing headache returns . I have some more panadol, put my facemask on and bury my head back under a pillow and go blissfully back to sleep. I don't remember much about this afternoon, I don't remember them taking the 2.30pm (6 hour) blood sample or vital sign check. I don't remember if the headache was as bad as my earlier one. I do remember having a very good sleep and feeling very safe - these Clinic beds and pillows sure are very comfy.

*4.30pm, Thursday:* I wake up from my headache induced slumber and feel hungry again, I have a nice dinner of teriyaki chicken, rice and salad and settle in to watch another movie on the big screen (maybe I will suggest a popcorn machine). Later, I send some more work e-mails and read some of my new book. This is just like a holiday – I have all of my needs met (food, recreation and quiet time away from the kids), only difference is there is no alcohol or caffeine and I have the odd headache every couple of hours.

*6.30pm, Thursday:* The project manager and the day shift nurses go home and the night nurses come on duty. I spend some time chatting to the three other people who are also in the clinic on another trial – interesting people. We all come from such different jobs and have very different life experiences – makes for fascinating conversation.

*8.30pm, Thursday:* They take my 12 hour blood sample and I feel quite tired. I have a shower, change into my yellow 'wonder-women' pyjamas, take some more panadol (to prevent my headache from returning) and go to sleep quite early (about 9.30pm). This lying about all day killing my malaria parasites has made me quite tired.

### Day 9 Drug Treatment Day (Friday)

*2.30am, Friday:* I wake-up (without a headache) to the night-shift nurse looking to take my 18 hour blood sample and vitals. She and I have a quick chat about how I am feeling and I go back to sleep.

*6.30am, Friday:* I wake up feeling really good (no headache). The guys on the other trial are all still asleep. I have a shower and get out of my pyjamas and have a lovely breakfast. All being well, I should get to go home this morning after the 24hour blood collection at 8.30m.

*8am, Friday:* I'm reading my newly downloaded novel on my kindle waiting for the 8.30am blood collection and my malaria killing headache returns and this time it is very, very angry. I bury my head under my pillow again - why is everything so bright and loud? I faintly remember the project manager and the lovely nurses coming to take my 8.30am blood and vital signs. They give me my morning malaria-killing drugs, some panadine and place a cool cloth on my forehead which feels really good against my headache. This time I also feel quite sick in the stomach. The project manager stays with me for some time, just talking to me - 'breath slowly, she says'. I focus on long, slow breaths, because I do not want to throw-up my malaria-killing medication. The Clinic staff are very caring and reassuring and I fall into a blissful slumber feeling very, very safe.

*Midday, Friday:* I wake up feeling somewhat better - that was a whopper of a headache - thank-god for sleep and for the Clinic staff - they really do take very good care of you here, way better than the care you would get from husband at home. The doctor comes and sees me and says that unless I make a dramatic improvement, I may have to stay at the Clinic overnight. I have some lunch and try my best to look bright and healthy for the return doctor visit later that afternoon. I want to go home.

*2.30pm, Friday:* I am watching a movie on the big screen television in the media room and chatting to the other trial participants, the nurse asks me to return to my bed for my 2.30pm blood sample and vitals (that's hour 30 – yey). I spend the afternoon lazing around, e-mailing, watching movies and reading – my headache has been reduced to a dull ache, I feel tired, but otherwise ok.

*4pm, Friday:* The doctor returns and is determines that I am healthy enough to leave after my 8.30pm blood collection (ie: The 36 hour time-point) and the evening dose of my malaria killing medication.

*6pm, Friday:* I have another lovely meal (this time its meatballs and pasta and a yogurt for desert). I chat to the three guys on the other drug trial (they are here until tomorrow morning). I have a dose of panadine to stop my headache coming back.

*8.30pm, Friday:* I have my evening dose of anti-malaria drugs, my 36 hour blood sample and my vitals. The nurse removes my cannula from my left forearm and I immediately feel really faint – lucky that I am lying down, otherwise, I think I would have fainted. It's funny how you can have so many needles with no problems and then feel faint so quickly - when the remove the final needle; how ironic. I leave the clinic and drive home. I never watched any of the DVD's that I bought, or played the X-Box. I spent most of my time in the clinic sleeping. I feel really satisfied with my ability to grow and then destroy malaria parasites. It was a good choice to pack the 'wonder-women' PJ's.

## Day 10 and Day 11 – Outpatient follow-up days (Saturday and Sunday)

*8am, Saturday:*

I return to the Clinic for my 48hour blood collection, my vitals and my second last dose of my malaria killing drugs. I have absolutely no fear of needles now. I had to bring my two young sons into the clinic this morning as my husband had to work. We head off for a day of fun in the park and go for a citycat cruise on the river. I still have a headache but it comes and goes and it is nowhere near as bad as the Thursday and Friday morning headaches.

*8pm, Saturday:* My husband and I celebrate my successful malaria killing experience with a beautiful dinner, no wine for me yet (it's our 11 year wedding anniversary today). I take my last dose of anti-malaria drugs and go to sleep.

*8.30am, Sunday:* I return to the Clinic for my final blood collection for the trial. My headaches are still occurring every now and again, they are not that bad – more annoying than painful. The nurses call the doctor to the clinic and he says they will check my blood samples to make sure everything is ok. He indicates that it is quite common for headaches after the anti-malarials, but they should disappear in the next few days. I go home and make the Father's day lunch with my two children – it's a great day. At dinner, I have my first glass of wine in two weeks.

# I'm off treatment...

## The week after the clinical trial

I catch up with the Clinic doctor again on Monday morning – it's an unscheduled visit, but the doctor wanted to touch base because of my ongoing headaches. He says that my blood tests have come back all normal. He reassures me that my headaches will go away. Around mid-afternoon on Tuesday, I realise that my headache has finally disappeared (for the first time in four and half days). It's such a good feeling. However, the headache comes back the next day and they continue to occur on and off for the rest of the week. They are probably from bad posture whilst looking down at my computer screen or not enough water. A dose of panadol or neurofen usually helps. I go to the gym on Friday morning and it's a really hard session, I feel really good after the workout. The headaches persist throughout the weekend; they are more an inconvenience than painful. I go fishing, to my 20-year school reunion and play soccer with my kids.

## Two weeks after the clinical trial

My headaches have been continuing throughout the week. I had a particularly nasty headache on Saturday lunchtime - I had to lie down for a day-time rest. I send a text message to the project manager at about 7pm on the Saturday night – I feel really bad about having to bother her on a Saturday night – but these headaches do not seem to be getting any better and I am getting worried. Within one hour of my text, I receive a phone call from the project manager and the doctor. We decide that I will come to the Clinic on Monday morning to do all my end-of-study tests.



## Day 28 - End of Study

I go to the Clinic on Monday morning and have my end-of study tests (ie: another ECG, more urine – they want even more evidence that I am not pregnant) and a whole host of different coloured tubes get filled with my blood. The doctor suggests that I have set up a headache cycle whereby the panadol/panadine and neurofen that I have been taking are what is actually causing my headaches. The solution is two days of panadiene and neurofen every 4-6 hours – this will break the cycle.

By the end of the week, the headaches have gone – the doctor's advice has broken the cycle. All of my blood tests have come back as perfectly normal and the Clinic have deposited my participant payment into my bank account as a compensation for my time during the trial.

## I'm off study...

### What I learnt from my clinical trial

*i) Expect the unexpected (it is an adventure after all).*

I entered into the clinical trial having read the participant information and consent form fully expecting to get a fever, shaking and chills from the malaria infection. Instead, I felt perfectly well the entire time that I had malaria, it wasn't until I took the anti-malarial drugs that my headaches started. I was amazed that headaches were the only symptom that I had – no fever, no chills, nothing – just the headaches.

*ii) The staff at QPharm will take really, really, really good care of you.*

If you are going to get sick, I can think of no better place to be than the Q-Pharm clinic. The nurses and project managers at Q-Pharm would have to be some of the most caring people on this planet. They take really good care of you and I always felt really safe and secure (especially during the drug treatment days when my headaches were really, really bad). They are also really good at using needles to collect blood – it really did not hurt at all – I think paper cuts or stubbing your toe hurts way more than a Q-Pharm nurse and their blood collection needle.

*iii) All of your friends and family will think you are crazy or desperate for money.*

Whenever I tell someone that I have been on a clinical trial and I got malaria – every single person says I must be mad. However, at no time did I think I was undertaking a high risk adventure. Everything in a clinical trial is very well considered and very well prepared; the safety controls are very, very strict. I think it is far more dangerous to drive to work, ride a pushbike or cross a road in the CBD than go on a clinical trial. I always felt very, very safe. I'll admit, the money that you get paid is nice, but I honestly did my malaria clinical trial for curiosity. Where else can you be paid to have a full health check, get malaria and get treated – all with excellent food, free big-screen televisions, internet and X-box.

*iv) Don't do a clinical trial for the money – it's not a good reason.*

Having just said that the money is nice, if you are thinking of doing a clinical trial solely for the money – then you probably will not make it to the end of the trial. When you are on your fourth day of twice daily visits to the Q-Pharm clinic to get yet another small amount of blood drawn or your second week of food and alcohol restrictions, if you are doing the trial for the money my gut feeling is that you would not bother to continue. Being on a clinical trial is hard work; you are asking a lot of your body on top of going to work and doing all of your other normal daily tasks. Do the trial for the right reasons – if you are curious about how powerful a tool your body can be for medical science then a clinical trial is the right experience for you. I enjoyed my clinical trial experience – this may sound strange, but I felt like I had contributed to making a difference to the world in a way that I never had before. I am very proud to have been a participant in a clinical trial and I would do it all again – even with malaria and headaches.

# Thanks for your interest in clinical trials.

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