

# CLINICAL TRIALS

## Combo Treatment for Hepatitis C

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### *A Parent's Story*

#### **Enduring a Clinical Trial, at Age 9**

By Gay K.

We adopted our daughter Marina at age 4 from Russia and discovered on routine screening that she was infected with the hepatitis C virus. Even though her pediatrician did not recommend she see a specialist, I found a pediatric gastroenterologist who confirmed her hepatitis C infection and recommended a liver biopsy.

The first liver biopsy was performed when she was age 5 and showed only mild liver inflammation. But this specialist had terrible communication skills. I was only able to talk with him as he passed in the hospital hallway after the biopsy. He didn't even stop walking! When I asked if I could have an appointment to discuss the biopsy, he said he was leaving for vacation and his clinic was booked both before and after the trip.

I immediately started looking for a new doctor! I did find another doctor at the same Children's Hospital whom I really liked. She explained a lot to me and patiently answered all my questions. The most troubling answer I got from her was: "We just don't know." There was and still is so much they don't know about hepatitis C infections in children. We saw her every six months thereafter, until she moved out of town to a new hospital.

In the meantime, I had been reading everything I could get my hands on and learning all I could from the Internet. I also joined four e-mail lists. The adult listservs were very distressing as I learned first-hand of the misery this disease causes.

Our new pediatric hepatologist, Dr. Lynda Brady at the University of Chicago Children's Hospital, performed a second biopsy when Marina was 9, about four years after the first biopsy. We discovered fibrosis (liver scarring) developing. That's when we made the decision to aggressively seek treatment when it became clear her liver disease was progressing.

We heard Schering-Plough Corporation was conducting a clinical trial of a combination

interferon and ribavirin treatment. Then the most difficult part began—making that decision to enter the trial, which was the most difficult decision of my life! I was basically making a critical decision for someone who could not make that decision herself. And because children had never been treated before with this particular combination drug treatment, there were many unknowns. I asked Dr. Brady and four other specialists for opinions.

While we were still struggling with the decision, my adult son one day said to me, “What have you got to lose?” That made me really think. The consequences of the disease are so severe that we felt that we had to be aggressive about seeking treatment. When we found out that Marina qualified for the interferon-ribavirin trial, we decided to go for it.

I had doubts many times during the 48 weeks of treatment, which she began in October 1999. I had doubts when I would hold her as she shook from the fevers. I had doubts every time I looked into her eyes and knew she just wasn't feeling quite right.

The severity of a drug's side effects are difficult to gauge in children like Marina. They don't anticipate or associate a side effect with the treatment. Children tend to take things as they come and roll with the punches.

She received an injection three days each week. She would get anxious every time she thought about it. She was frequently nauseated and tired, and had trouble staying focused at times.

We gave her ibuprofen each evening with each shot, but after the Monday night injection she would have a bounce-back effect from the Interferon and would still have a fever on Tuesday morning. It was tough getting her out of bed and taking her to school even when she had a fever.

But after another dose of ibuprofen in the morning, the fever would usually disappear by school time, but she looked especially wiped out on those days. She also dealt with dry skin on various parts of her body, especially on her fingertips. Between her dry skin and anxiety, she would pick at the skin around the fingernails until it bled. (Just what you want, a child with hepatitis at school with bleeding fingertips!)

After we finished the treatment, the nausea disappeared, her appetite returned and there were no more fevers! We noticed that her anxiety level had gone way down and she began to leave her cuticles alone.

## COMBO TREATMENT

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Marina has hepatitis C virus Genotype 2A. Some doctors recommend only six months of treatment for this genotype. We again went through agony deciding the length of Marina's treatment. Should we pull her off the medication after six months, or continue on with the full 48 weeks?

After four weeks of treatment she tested negative for the virus in her bloodstream. When the hepatitis C RNA disappeared, it was tempting to just pull the treatment plug after six months. But we knew the best chance of a sustained response was to undergo the full 48 weeks of treatment.

Again, I asked opinions from every professional I could. I received varying assessments, some recommended stopping after the six months, some suggested we continue for the full 48 weeks. We did complete the full 48 weeks.

We ended treatment on Oct. 6, 2000, and tests conducted six months after treatment in April, 2001, still show no signs of the virus in her blood!

Three weeks after her treatment ended, her teacher commented on how things were just "clicking" for Marina. She was able to pay attention, was more energetic, more involved in class and much less anxious. I thought it was interesting because neither her teachers nor I had noticed these symptoms as they had crept up gradually, but their absence was striking!

The difficulty of treatment took its toll on our family. Dad gave her the injections, I was the supporter and held her during the shots. There were problems traveling while taking the medication, accidental needle sticks and slumber parties to deal with.

There was also the distance we had to travel for appointments, a seven-hour trip one-way. We went every week during the first five weeks of treatment and chalked up a grand total of 20 trips during 48 treatment weeks.

The long drive meant we had to leave on Sunday. We had our appointment early Monday morning and drove home.

Missing so many Mondays, which is when the week's school assignments are given, caused Marina some difficulties in school. But the travel was worth it – we knew we were working with specialists who knew what they were doing.

But when it came time for the injections, so many times we wished we could just take the shots for her.

Would we do it again? Definitely! When I asked Marina recently if she would recommend treatment to other kids, she said she emphatically would.

She doesn't want to have the hepatitis C virus. She wants to be just like all other kids. She told me, "I'll do whatever it takes to get rid of the hepatitis C!" She is one tough kid!

She is currently exchanging letters with two kids who are currently in treatment. Her advice to them is, "Hang in there, don't be afraid."



*artwork by Marina*