

Trial using Kre-Celazine for Pain

Guidelines
FDA

Author
Jeff Golini

Study Completed on January 27th, 2008

Performing Laboratory

BioCeuticals Research & Development Laboratory
Montana Division
2376 Main Street
Room 14
Billings, MT 59105

BRDL Study No.
1252

(1 of 4)

Introduction:

A single male youth was identified, screened and used for the study. The subject was born with double club feet which included a short Achilles tendon.

A club foot is a birth defect which involves the foot being twisted in (inverted) and down. This defect is very common and occurs in one of every 1,000 live births.



There are different causes for a club foot, but the main one is something called Edward's syndrome (a genetic defect caused by the presence of three, instead of two, copies of *chromosome 18*).

Club feet can be treated with braces or splints to correct the positions or by castings. If the defect is more serious, then surgery of the soft tissue of the bone is necessary. If the child was also born with a short Achilles tendon, then a surgery called clipping must be performed to release the tension. If surgery is needed, then it is usually preceded by a lot of pain. The surgery can lead to scar tissue developing in the child's foot. Additional surgery may be needed to remove the build up of the unwanted scar tissue.

The Achilles tendon is a tendon of the posterior leg. It serves to attach the gastrocnemius (calf) and soleus muscles to the calcaneus (heel) bone.

The subject was casted every two weeks until he was six months old. At the age of one year, subject had his first surgery on both feet. His Achilles was spliced and lengthened and his bones repositioned. At age seven, the subject once again had surgery on his left foot to reposition the tendon on the top. This tendon was over powering the rest of the tendons and causing his foot to turn in again. During surgery subject also had to have one bone shortened and another lengthened.

Subjects Current Problems:

By age nine, even though the club feet were healed, a new ailment occurred. The young subject's feet were extremely sensitive to weather changes and a simple activity such as walking caused excruciating pain. To help with the pain, treatment included ibuprofen, glucosamine, omega 3, calcium and magnesium pills. None of these treatments stopped the pain completely and every day was another day of achiness and potential for pain. By most evenings the subject's feet hurt so bad he would just have to sit. If subject walked too much, like going shopping, the pain became so great he would have to ride in the cart. The doctors said it was something he would just have to live with or wait until he was order to try some more powerful pain killers. It was hypothesized that the subject may have chronic inflammation. Pain pills only masks the problem, but never deals with the cause.



Subjects' feet at 1 month



Subjects feet at 12 months before first surgery



Subjects feet after first surgery in March 2000



Subjects left foot before second surgery in 2006



**Subjects left foot after second surgery in 2006
(3 of 4)**

Procedures:

The subject, being nine years old, was administered 750 mg of Kre-Celazine a day orally for three months. The dose was taken in the A.M. on an empty stomach. No changes were made to subjects' diet or daily activities.

Summary:

Upon awaking the morning before the first dose, the subject reported that both feet were in pain. Less than eight hours after the first dose, the subject reported that his feet no longer hurt and the pain was gone. He said, "Those pills must be doing something."

By the end of the second day, the subject reported that his pain had disappeared. The subject said, "This Kre-Celazine works better than anything else I have ever been given."

By the beginning of the third morning the subject reported he no longer had that aching pain.

By the end of the first week the pain was completely gone. Not only was the pain gone, but it never returned. For the past several years, ever since the subject could talk, his mornings started out with a discussion on how badly his feet hurt. Now the morning discussions start out with how good his feet feel. At the end of the 3-month study, the subject is still pain free. As a matter of fact, he can now run, jump and play like normal kids without the fear of pain and having to rest.

Conclusion:

Kre-Celazine completely healed the chronic inflammation in this young subjects feet that caused so much pain that he could not lead a normal nine year olds' life of running and jumping. The medical arena tried the normal over-the-counter pain pill ibuprofen and also prescribed a few popular dietary supplements such as glucosamine and omega 3's. None of these worked very well and all along the pain was still present.

After less than eight hours of the first dose, the subject reported his pain disappeared and after just one week it was completely gone. When he is asked how his feet feel, he now response by saying "I feel like I want to just start walking and never stop."

This study proves that Kre-Celazine out performed ibuprofen, glucosamine, omega 3's, and a variety of other over-the-counter pain medications and dietary supplements hands down. Not only did it get rid of the pain, but the subject's mobility came back and *The Pain Never Did*.



A picture of the happy subject at age 9 using Kre-Celazine. He is happy because his pain is now gone for the first time in his life. He is able to lead a normal life of running and jumping like all the other kids his age.