

ZYN2-CL-031 Study Overview for Parents/Guardians

The Sponsor of this study is testing a clear topical gel applied twice daily to the upper arms and shoulders. The name of the topical gel is ZYN002.

ZYN002 is manufactured cannabidiol (CBD). CBD is part of the cannabis/marijuana plant but does not have the effect on the brain that marijuana has. The study drug is in a foil ‘sachet’ (much like the packaging of a single serving of ketchup).

The purpose of this study is to investigate whether ZYN002 gel is effective in patients with 22q11.2 Deletion Syndrome (22qDS).

There will be a Screening Visit (Visit 1) to determine if your child meets the study requirements. If they do they will be enrolled into the study and receive 14 weeks of treatment. If your child is taking anti-epileptic drugs (AEDs) they will continue to receive a lower dose of ZYN002 for another week (Week 15) or two weeks (Week 15 and Week 16) instead of just stopping study treatment.

Depending on your child’s weight will determine whether they receive 250 mg or 500 mg of ZYN002 on a daily basis. If they take 250 mg daily this will be a total of 2 sachets per day. If they take 500 mg daily this will be a total of 4 sachets per day. Study drug is applied twice a day approximately every 12 hours.

The first dose of study medication will be applied at the Study Doctor’s office, which is Visit 2. At Visit 2 you will be provided study drug until the next visit which is Visit 3. Visit 3 is approximately 6 weeks after Visit 2. At Visit 3 you will be provided study drug until Visit 4 which is approximately 8 weeks after Visit 3. If your child does not take AEDs they will complete the end of study (EOS) at Visit 4. If your child takes AEDs you will be provided a reduced amount of study drug to continue to apply for one or two more weeks (Week 15 or Week 15 and 16). Your child will complete the study at Visit 5 (either Week 15 or Week 16).

Treatment Period				ONLY Patients Taking AEDs		
Visit 1	Visit 2	Visit 3	EOS Visit 4	Taper Period		
					EOS Visit Wk 16 OR Wk 17	
Screening	Day 1	Week 6	Week 14	Week 15	Week 16	Week 17
				Week 15 OR Week 15 AND 16		

As a parent/caregiver you have a very important role to play in this study, as you will:

- Apply study drug to your child’s upper arms/shoulders twice a day – the application should be approximately 10 to 14 hours apart.
- Starting the first day of gel application you will record in a Skin Irritation Diary whether your child is experiencing any redness where the gel was applied. This will be done **every** evening before applying the second daily drug dose.
- At each study visit, the parent/caregiver must complete questionnaires to rate your child’s behavior and symptoms. There are approximately 4 to 5 questionnaires that you will complete at the Screening Visit 1 and study Visits 2, 3, and 4.