

## A Randomized, Double-Blind, Placebo-Controlled Multiple-Center, Efficacy and Safety Study of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome - RECONNECT

**Status:** Recruiting

### Eligibility Criteria

**Sex:** Male or Female

**Age Group:** 3 years to 23 years old

This study is NOT accepting healthy volunteers

#### Inclusion Criteria:

- ages 3 to less than 23 years - resides with caregiver who will continue to provide consistent care throughout the study - diagnosis of Fragile X Syndrome (FXS) through molecular documentation - body mass index between 12-30 kg/m<sup>2</sup> - in generally good health based upon the results of medical history, physical exam, 12-lead ECG and clinical laboratory test results - contact study staff for additional requirements

#### Exclusion Criteria:

- women who are pregnant, nursing or planning a pregnancy - has transitioned to independent living or living in a residential facility such as a university setting or congregate care - use of cannabis or any THC or CBD-containing product within 3 months first study visit or during the study - positive drug screen, including ethanol, cocaine, THC, barbiturates, amphetamines (unless prescribed), benzodiazepines (except midazolam or comparable administered for blood draws and ECG collection), and opiates - additional medical or mental health diagnosis (study staff will review)

### Conditions & Interventions

#### Conditions:

Rare Diseases

#### Keywords:

Fragile X Syndrome

### More Information

**Description:** The purpose of this study is to investigate how effective and safe ZYN002, a transdermal gel, is in participants with FXS. The drug product ZYN002 is a pharmaceutically manufactured CBD. It is being developed as a clear gel that can be applied to the skin (called transdermal delivery), to provide consistent, controlled levels of CBD in the blood when it is given twice a day. Participants will be assigned by chance to get one of the following study treatments: Active study drug – ZYN002 or placebo. Assigning study drug by chance is called “randomization,” and it is an important part of testing an experimental study drug. Participants will be randomly assigned to study treatment according to a computer program and will have 1 in 2 chance of receiving the active study drug.

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**Phase:** Phase 3

#### IRB

**Number:** SITE00001338

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