

# OPN-375 Efficacy and Safety in Adolescents With Bilateral Nasal Polyps

NCT03747458

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Status	RECRUITING
Phase	Phase 3
Sponsor	Optinose US Inc.
Enrollment	72 participants

## Key Eligibility Criteria

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### Inclusion (25)

- Male or female subjects aged 12 to 17 years, inclusive, at time of Visit 1 (Screening).
- Female subjects, if sexually active, must,
  - be practicing an effective method of birth control (e.g., prescription oral contraceptives, contraceptive injections, contraceptive patch, intrauterine device, double-barrier method [e.g., condoms, diaphragm, or cervical cap with spermicidal foam, cream, or gel], or male partner sterilization) before entry and throughout the study, or
  - be surgically sterile (have had a hysterectomy or bilateral oophorectomy, tubal ligation, or otherwise be incapable of pregnancy), or
  - be abstinent.

... and 20 more (see full listing online)

### Exclusion (18)

- Pregnancy or lactation
- Has a history of cystic fibrosis
- Have used XHANCE (fluticasone propionate) nasal spray within the past 2 months
- Inability to achieve bilateral nasal airflow for any reason, including nasal septum deviation
- Inability to examine both nasal cavities for any reason, including severe nasal septum deviation

... and 13 more (see full listing online)

## Locations (40 total)

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Clinical Research Center of Alabama, Birmingham, Alabama, United States  
San Tan Allergy & Asthma, Gilbert, Arizona, United States  
Kern Research, Bakersfield, California, United States  
... and 37 more locations

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<https://clinicaltrials.gov/study/NCT03747458>

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