Informations about the disease

What is Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)?

CRSwNP is a *chronic inflammatory disease of the nose* and *sinuses with co-existence of nasal polyps* and *chronic symptoms of sinusitis* which may severely impact a patient's quality of life.

Nasal polyps are *swellings* or *"lumps"* in the nose that *can block the nose* and cause *feelings of congestion/obstruction*. Patients with CRSwNP also commonly experience a *reduced* or *lost sense of smell*, *runny nose*, *post-nasal drip*, and *facial pain*.

Do you qualify for this study?

You may be eligible if you:

- Are between *18 and 70 years old*
- Have *nasal polyps* that your doctor has *identified,* despite having used corticosteroid treatment for at least 2 months
- Are experiencing the *following symptoms:*
  - ◊ Nasal congestion, blockage, and/ or obstruction
  - ◊ Partial loss of smell (hyposmia) or total loss of smell (anosmia), and/or anterior and/or posterior rhinorrhea

Where can I find more information?

For *more information* on this clinical research study or to see if you may qualify to participate, please contact:

Site Information:

Pharmaceutical Research & Consulting
5499 Glen Lakes Drive
Dallas, TX 75231

Site contact name and details:

Rebecca Lindsey, Study Recruiter
rebecca.lindsey@daac-prc.com
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ACT18207

Chronic Rhinosinusitis

with Nasal Polyps (CRSwNP)
Clinical Research Study

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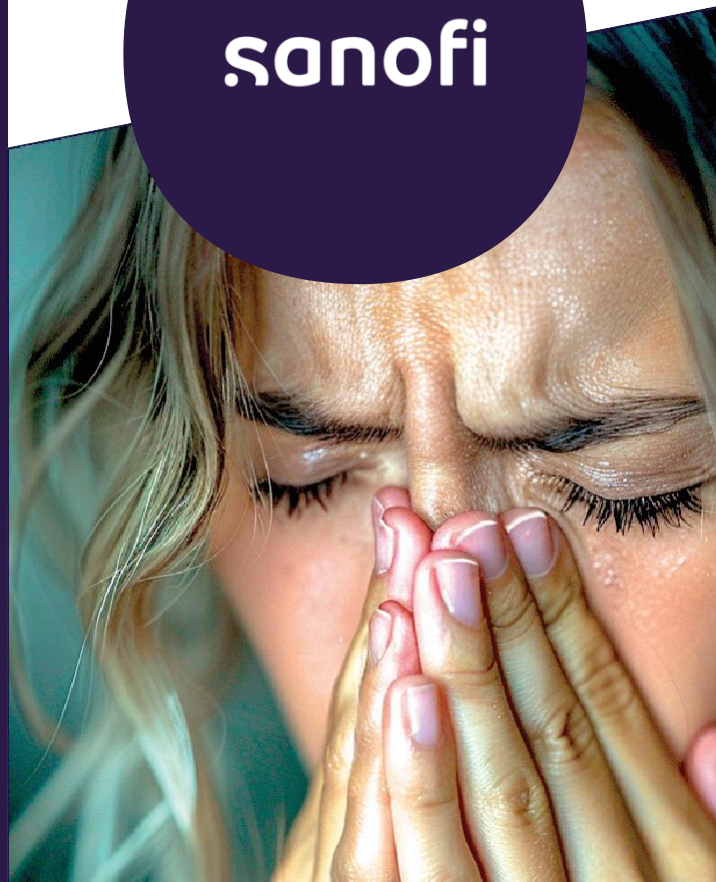

What are Clinical Research Studies?

Clinical research studies are used to *show if/how a study medication works* and *to find out if it is safe*.
They can also be referred to as clinical research trials.

Qualified doctors run clinical research studies. The doctors *are responsible for the study-related care of the people* that participate *(or enroll)* in these studies.

The roles and procedures of this study were *reviewed* and *approved by an Independent Committee*.
Independent committees *(called Ethics Comitees or ECs)* made up of *medical* and nonmedical people who also *watch over clinical research studies* to make sure that the people who enroll are *told everything they need to know* and that *they are protected*.

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What is the ACT18207 Study?

Study Purpose

The ACT18207 study is a Clinical Research Study conducted to *determine if a new study medication*, that is not yet approved by the Health Authority, is *safe* and *effective as a treatment* for *Chronic Rhinosinusitis with Nasal Polyps*.

Study Medication

The study medication is *lunsekimig* and is an *injectable solution*. It may represent a novel therapeutic approach for CRSwNP patients whose *pathology is inadequately controlled with standard available therapies*.
Patients who enroll in the study will either receive *lunsekimig* or *placebo injections* under the skin *every 4 weeks during the 6 months of the treatment period*.
They will also r*eceive mometasone furoate nasal spray* daily during the whole study duration. The placebo looks just like the study drug but does not contain any active medicine. This gives the researchers something to compare to the study drug to better understand its effects.
Patients who enroll in the study *have the same chances of receiving the study drug as or receiving the placebo*.

Study periods

(~10 months)

SCREENING PERIOD
[4 weeks]
1 on-site appointment during which patients eligibility to enroll in the study will be verified.

TREATMENT PERIOD
[~6 weeks]
8 on-site appointments every 2 to 4 weeks during which patients will have examinations and receive either study treatment or placebo administrations

FOLLOW-UP PERIOD
[16 weeks]
2 on-site appointments to follow-up patients after the treatment period

Which tests are planned during the study?

During study appointments, patients who enroll in the study will have examinations to check their health. They will not have all of them at each appointment.

Some of the tests include:

- Vital signs
- Physical examination
- Respiratory examiniation
- Blood test
- Imaging *(such as CT scan and nasal endoscopy)*

Patients who enroll in the study will also *fill out questionnaires* and answer questions about their overall health, use of other medications during the study, and overall quality of life.