

# Evaluating vidian neurectomy efficacy in allergic rhinitis via nasal mucosal response

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<b>Registration date</b> 06/03/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/03/2025	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The primary treatments for allergic rhinitis (AR) include drug therapy, immunotherapy and surgical interventions. Vidian neurectomy (VN), a targeted surgical method, proposes severing the vidian nerve to mitigate autonomic responses that exacerbate AR symptoms. The current evaluation of VN efficacy primarily relies on subjective symptom scores from patients, lacking objective indicators. This study proposes using nasal mucosal autonomic nerve responses, measured via an opisthenar sympathetic skin response (SSR) instrument (SSR-1000, BIOPAC, CA, USA), as an objective indicator of VN efficacy. This study will validate the use of this measurement as a reliable indicator of surgical success for patients with severe AR and provide a more quantitative assessment of VN's impact on AR symptoms.

### Who can participate?

Thirty-five patients with moderate to severe AR and 35 healthy controls were included.

### What does the study involve?

Patients in the experimental group underwent electrocoagulation of the VN with a low-temperature plasma knife (Coblator II, ArthroCare, USA).

### What are the possible benefits and risks of participating?

**Benefits:** Post-VN, damage or disruption to the parasympathetic nerve fibres in the nasal mucosa leads to constriction of the nasal submucosal blood vessels and diminished glandular secretion, thus alleviating symptoms such as nasal congestion, rhinorrhoea, sneezing and nasal itching. Nasal mucosal autonomic nerve response is expected to provide a reliable, objective measure for evaluating the effectiveness of VN in treating AR.

**Risks:** Long term attention should be paid to the long-term efficacy and potential complications of VN.

### Where is the study run from?

Yulin City First Hospital of Yan'an University, China

When is the study starting and how long is it expected to run for?  
July 2022 to December 2024

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Dr Yan Niu, Niuyan\_2024@yeah.net

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Yan Niu

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Use of nasal mucosal autonomic nerve response in efficacy evaluation of vidian neurectomy for allergic rhinitis: a prospective study

### Study objectives

To use nasal mucosal autonomic nerve responses, measured via an opisthenar sympathetic skin response (SSR) instrument (SSR-1000, BIOPAC, CA, USA), as an objective indicator of vidian neurectomy efficacy.

### Ethics approval required

Ethics approval required

## **Ethics approval(s)**

approved 01/07/2022, The Ethics Committee of Yulin City First Hospital of Yan'an University (No. 93 Yuxi Avenue, Yuyang District, Yulin, 719000, China; +86 18992275370; Llinzheng11@outlook.com), ref: [2022] Ethical Review No. (061)

## **Study design**

Single-center interventional non-randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Evaluate the use of nasal mucosal autonomic nerve responses as an objective indicator for assessing the efficacy of vidian neurectomy (VN) in treating allergic rhinitis (AR)

## **Interventions**

Patients in the experimental group underwent electrocoagulation of the vidian nerve under general anaesthesia, utilising a low-temperature plasma knife (Coblator II, ArthroCare, USA). The control group consisted of 35 healthy individuals. The nasal mucosal autonomic nerve response was induced through respiratory stimulation. Measurements were conducted before and 1 month after the patients underwent low-temperature plasma VN. Electrical signals from the nasal mucosa and the back of the hand were recorded using an SSR instrument.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Waveform of nasal mucosal autonomic responses and sympathetic skin response measured using waveforms and amplitude of electrical signals before and 1 month after the patients underwent low-temperature plasma VN

## **Key secondary outcome(s)**

The effect of comorbidities (nasal polyps, sinusitis and a deviated nasal septum) on surgery efficacy measured using the amplitude of autonomic nervous responses in the left and right nasal mucosa of patients with three types of comorbidities before and 1 month after the patients underwent low-temperature plasma VN

## **Completion date**

31/12/2024

# **Eligibility**

## **Key inclusion criteria**

1. Patients diagnosed with moderate to severe AR without age limitation
2. Selection adhered to the ARIA guidelines, which require AR symptoms to persist for over 4

weeks, occurring more than 4 days per week and lasting longer than 4 hours each day  
3. Candidates were either unresponsive to conventional drug treatments or exhibited intolerance

**Participant type(s)**

Healthy volunteer, Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

81 years

**Sex**

All

**Total final enrolment**

70

**Key exclusion criteria**

1. Any nasal surgeries within the 6 months before the study
2. Pregnancy or lactating
3. Prior medical history or conditions that could influence autonomic nerve function or inflammatory responses, such as severe cardiovascular diseases, neurological disorders or other types of rhinitis
4. A history of autoimmune disorders, such as rheumatoid arthritis
5. Use of medications affecting the autonomic nervous system within the last 3 months, such as beta-blockers or immunosuppressants

**Date of first enrolment**

01/01/2023

**Date of final enrolment**

01/03/2024

**Locations****Countries of recruitment**

China

**Study participating centre**

Yulin City First Hospital of Yan'an University  
No. 93 Yuxi Avenue, Yuyang District

Yulin  
China  
719000

## Sponsor information

### Organisation

Yan'an University

### ROR

<https://ror.org/01dyr7034>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr. Yan Niu, [Niuyan\\_2024@yeah.net](mailto:Niuyan_2024@yeah.net)

### IPD sharing plan summary

Available on request