

Evaluating vidian neurectomy efficacy in allergic rhinitis via nasal mucosal response

Submission date 03/03/2025	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/03/2025	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 05/03/2025	Condition category Respiratory	☐ Individual participant data ☐ 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

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

Yulin

China

719000

+86 18891521582

Niuyan_2024@yeah.net

Additional identifiers

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)

Primary study design

Interventional

Study design

Single-center interventional non-randomized controlled trial

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

IPD sharing plan summary

Available on request