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Evaluating vidian neurectomy efficacy in allergic rhinitis via nasal mucosal response

Submission date
03/03/2025

Recruitment status
No longer recruiting

Registration date
06/03/2025

Overall study status
Completed

Last Edited
05/03/2025

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures
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

Overall study start date
01/07/2022

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
81 Years

Sex
Both

Target number of participants
70

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

Sponsor details
Yulin City First Hospital of Yan'an University
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Llinzheng11@outlook.com

Sponsor type
Hospital/treatment centre

Website
https://www.ylsdyyy.com/

ROR
https://ror.org/01dyr7034

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/06/2025

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