# The Efficacy of Octenidine in Sinusitis compared to standard of care

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## Main Information

**Primary registry identifying number**
LBCTR2020023398

**Protocol number**
LAUMCRH.RH2.4/Dec/2019

**MOH registration number**

**Study registered at the country of origin**
Yes

**Study registered at the country of origin: Specify**

**Type of registration**
Prospective

**Type of registration: Justify**
N/A

**Date of registration in national regulatory agency**
01/03/2020

**Primary sponsor**
Schülke

**Primary sponsor: Country of origin**
Germany

**Date of registration in primary registry**
20/02/2020

**Date of registration in national regulatory agency**
01/03/2020

**Public title**
The Efficacy of Octenidine in Sinusitis compared to standard of care

**Acronym**

**Scientific title**
The Efficacy of Octenidine in Sinusitis compared to standard of care

**Acronym**

**Brief summary of the study: English**

Rhinosinusits is one of the most common infections worldwide treated mainly with antibiotics. In the era of emerging antibiotic resistance, we should be more meticulous in prescribing antibiotics. Antiseptics are another antibiotic sparing strategy especially when used locally in wounds and other
sites of infection like the sinuses. Octenidine, the active ingredient in Octenisan nasal gel, is an antiseptic that has been tested and used on human skin and wounds for many years. It is very effective in eradicating bacterial pathogens, and above all, it is safe to use on mucosal surfaces. The purpose of this study is to assess the efficacy of this gel in treating acute bacterial rhinosinusitis or exacerbations
of chronic rhinosinusitis.

**Brief summary of the study: Arabic**

يعدّ التهاب الجيوب الأنفية من أكثر الالتهابات التي يتم علاجها بالمضادات الحيوية عادة. في وقت تظهر فيه مقاومة للمضادات الحيوية أكثر فأكثر، يجب علينا أن نكون حذرين جداً عند وصف المضادات الحيوية. وتعتبر المطهرات استراتيجية أخرى لنتفادى بها المضادات الحيوية، لا سيّما عند استخدامها بطريقة موضعية على الجروح ومواقع التهابات أخرى مثل الجيوب الأنفية. ويعدّ الأوكتنيدين، المكوّن الفعّال في جل أوكتنيسان للأنف، مطهّراً تم اختباره واستخدامه على البشر لسنوات عديدة. إنه فعّال جداً في إزالة البكتيريا المسببة للأمراض، والأهم يمكن استخدامه على الأسطح المخاطية بكل أمان. الغرض من هذه الدراسة هو تقييم فاعلية هذا الجل في علاج التهاب الجيوب الأنفية الحاد أو حالات تفاقم التهاب الجيوب الأنفية المزمن.

**Health conditions/problem studied: Specify**

Acute Bacterial Rhinosinusitis
ARS is defined as symptomatic inflammation of the nasal cavity and paranasal sinuses that lasts less than four weeks. The most common

etiology of ARS is viral; hence the treatment focuses on symptomatic management as it typically resolves within 7-10 days. Acute Bacterial Rhinosinusitis (ABRS) occurs in about 0.5-2%. Patients with ABRS are observed or treated with antibiotics. According to the Infectious Disease Society of America we start antibiotic therapy after diagnosis for patients who do not have good follow up, in patients who have been observed and who have worsening symptoms or fail to improve within a seven-day period or patients with severe symptoms

Exacerbations of Chronic Rhinosinusitis
Chronic rhinosinusitis (CRS) may be broadly defined as an inflammatory disorder of the paranasal sinuses and linings of the nasal passages that lasts 12 weeks or longer. More precisely, it is a heterogeneous group of related disorders that share certain clinical and pathologic features.

**Interventions: Specify**

Patients will be recruited from multiple departments: ENT, Family Medicine, Infectious Diseases and Emergency Medicine.
After determining if the patient falls under the guidelines of ABRS or CRS exacerbation described in the introduction stated above, they will be randomly assigned to receive either standard of care or Octenidine.
The patients' SNOT22 score will be calculated and few questions about the patients' demographics will be answered before the treatment starts (initial assessment). (T0)
Four days after initiating the treatment, a follow up phone call will be conducted to ask few questions and calculate the new SNOT22 score. An average of the new SNOT22 score for both groups will be calculated. A difference of 10% or less will be considered as insignificant concluding that Octenidine is as effective as antibiotics with the benefit of reducing antibiotic resistance. We will also report the number of patients who dropped out or were switched to a different treatment. (T1)
Ten days after initiating treatment (last day of treatment) the same process that was carried out on day 4 will be conducted again and the results will be reported. (T2)
Two weeks after stopping treatment, the same process will be carried out. (T3)
Octenidine will be given twice per day for 10 days. It is applied in each nostril posteriorly, followed by a gentle squeeze on the anterior nares to push the gel into the nasal cavity. After few minutes, due to body temperature, the gel may liquify and run through the nostrils. In that case, the patient is advised to wipe gently using a tissue without blowing their nose and flushing the gel out.

**Key inclusion and exclusion criteria: Inclusion criteria**

□CRS: Patients (male or female) at the age of 18 or above who fit the criteria for exacerbation in CRS :

□Twelve weeks or longer of two or more of the following signs and symptoms:
omucopurulent drainage (anterior, posterior, or both)
onasal obstruction (congestion)
ofacial pain-pressure-fullness
odecreased sense of smell.

□AND inflammation is documented by one or more of the following findings:
opurulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region.
oradiographic imaging showing inflammation of the paranasal sinuses.

□ABRS: Patients at the age of 18 or above who fit the criteria for ABRS

**Key inclusion and exclusion criteria: Gender**

Both

**Key inclusion and exclusion criteria: Specify gender**

**Key inclusion and exclusion criteria: Age minimum**

18

**Key inclusion and exclusion criteria: Age maximum**

100

**Key inclusion and exclusion criteria: Exclusion criteria**

□Exclusion criteria for both ABRS and CRS:
oPatients who are below the age of 18.
oPatients who are pregnant.
oPatients who have received antibiotics.
oPatients who are immunocompromised.
oPatients who have high grade fever defined as 38.5C and above
oPatients with known allergy to octenidine.
oPatients with contraindications to octenidine.
oPatients who scored severe on the SNOT22 score
oPatients who are receiving systemic glucocorticoid therapy.

**Type of study**

Interventional

**Type of intervention**

Pharmaceutical

**Type of intervention: Specify type**

N/A

**Trial scope**

Therapy

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

Randomized controlled trial

**Study design: Masking**

Open (masking not used)

**Study design: Control**

Active

**Study phase**

3

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Single

**Study design: Specify assignment**

N/A

**IMP has market authorization**

Yes, Lebanon and Worldwide

**IMP has market authorization: Specify**

Worldwide

**Name of IMP**

Octenidine

**Year of authorization**

**Month of authorization**

**Type of IMP**

Others

**Pharmaceutical class**

Antiseptic and Disinfectant

**Therapeutic indication**

Octenidine is an established antiseptic to be used on the skin, mucous membranes and wounds prophylactically as well as therapeutically in a growing field of applications and could replace classical antiseptics like chlorhexidine. It is easy and safe to handle, chemically stable, not inflammable, without resistance development and low toxicity to man and the environment alike.

Octenisan Nasal Gel is used for moistening and decontamination of nasal vestibules by physical cleansing and supportive wound treatment of lesions of the nasal epithelium.

**Therapeutic benefit**

Possible treatment of bacterial rhinosinusitis without the use of antibiotics, in the era of antimicrobial resistance and multidrug resistant organisms

**Study model**

N/A

**Study model: Explain model**

N/A

**Study model: Specify model**

N/A

**Time perspective**

N/A

**Time perspective: Explain time perspective**

N/A

**Time perspective: Specify perspective**

N/A

**Target follow-up duration**

**Target follow-up duration: Unit**

**Number of groups/cohorts**

**Biospecimen retention**
None retained

**Biospecimen description**
None retained

**Target sample size**
40

**Actual enrollment target size**

**Date of first enrollment: Type**
Anticipated

**Date of first enrollment: Date**
02/03/2020

**Date of study closure: Type**
Anticipated

**Date of study closure: Date**
01/03/2021

**Recruitment status**
Pending

**Recruitment status: Specify**

**Date of completion**

**IPD sharing statement plan**
No

**IPD sharing statement description**
NA

**Additional data URL**

**Admin comments**

**Trial status**
Approved

## Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|---|---|
| LAU IRB | LAUMCRH.RH2.4/Dec/2019 |

## Sources of Monetary or Material Support

| Name |
|---|
| Schulke company will provide the Octenisan Nasal Gel free of charge for the use in the study. There is no other additional monetary support. |

## Secondary Sponsors

No Sponsors

## Contact for Public/Scientific Queries

| Contact type | Contact full name | Address | Country | Telephone | Email | Affiliation |
|---|---|---|---|---|---|---|
| Public | Harout Kolanjian | LAUMC-RH, Zahar Street, Achrafieh | Lebanon | 01 200 800 | harout.kolanjian@lau.edu | LAUMC-RH |
| Scientific | Roula Husni - Samaha | LAUMC-RH, Zahar Street, Achrafieh | Lebanon | 01 200 800 | roula.samaha@laumcrh.com | LAUMC-RH |

## Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|---|---|---|---|
| LAUMC-RH | Roula Husni Samaha | Infectious Diseases | Approved |

## Ethics Review

| Ethics approval obtained | Approval date | Contact name | Contact email | Contact phone |
|---|---|---|---|---|
| Lebanese American University- University Medical Center Rizk Hospital | 04/12/2019 | Christine Chalhoub | christine.chalhoub@lau.edu.lb | +961 9 547254 ext. 2340 |

## Countries of Recruitment

| Name |
|---|
| Lebanon |

## Health Conditions or Problems Studied

| Condition | Code | Keyword |
|---|---|---|
| Acute Bacterial Rhinoosinusitis | Acute sinusitis (J01) | ABRS |
| Chronic Rhinosinusitis | Chronic sinusitis (J32) | CRS |

## Interventions

| Intervention | Description | Keyword |
|---|---|---|
| Octenidine | Intranasal application of Octenidine twice daily for ten days | Group 1 |
| Standard of Care | The use of oral antibiotics for treatment of bacterial sinusitis (standard of care) | Group 2 |

## Primary Outcomes

| Name | Time Points | Measure |
|---|---|---|
| Treatment of Rhinosinusitis | 10 days | change in SNOT22 score |

## Key Secondary Outcomes

| Name | Time Points | Measure |
|---|---|---|
| Decreasing the use of antibiotics, and hence decreasing the antimicrobial resistance on the long run | years | Antibiotic susceptibility profile of pathogens |

## Trial Results

**Summary results**

**Study results globally**

**Date of posting of results summaries**

**Date of first journal publication of results**

**Results URL link**

**Baseline characteristics**

**Participant flow**

**Adverse events**

**Outcome measures**

**URL to protocol files**