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 لتتفادى 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