



The Efficacy of Octenidine in Sinusitis compared to standard of care

22/11/2024 00:08:25

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

Rhinosinusitis 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

يعد 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 استراتيجيات أخرى لتفاديها المضادات الحيوية، لا سيما عند استخدامها بطريقة موضعية على الجروح ومواقع التهابات أخرى مثل الجيوب الأنفية. ويعد الأوكتنيدين، المكون الفعّال في جل أوكتنيسان للأنف، مطهراً 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:

o mucopurulent drainage (anterior, posterior, or both)

o nasal obstruction (congestion)

o facial pain-pressure-fullness

o decreased sense of smell.

AND inflammation is documented by one or more of the following findings:

o purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region.

o radiographic 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:

o Patients who are below the age of 18.

o Patients who are pregnant.

o Patients who have received antibiotics.

o Patients who are immunocompromised.

o Patients who have high grade fever defined as 38.5C and above

o Patients with known allergy to octenidine.

o Patients with contraindications to octenidine.

o Patients who scored severe on the SNOT22 score

o Patients 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: Control

Active

Study design: Purpose

Treatment

Study design: Assignment

Single

IMP has market authorization

Yes, Lebanon and Worldwide

Name of IMP

Octenidine

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: Specify model

N/A

Time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration**Number of groups/cohorts****Study design: Masking**

Open (masking not used)

Study phase

3

Study design: Specify purpose

N/A

Study design: Specify assignment

N/A

IMP has market authorization: Specify

Worldwide

Year of authorization**Month of authorization****Study model: Explain model**

N/A

Time perspective: Explain time perspective

N/A

Target follow-up duration: Unit



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 Rhinosinusitis	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