



Method for Standard Operation Procedure, Clinic Methods

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Method for Standard Operation Procedure, Clinic Methods

This document provides guidance for writing a standard operating procedure (SOP) who describes clinical methods in ozone therapy. See ISCO3 QAU/00/22 guidelines, for details of the type of information to be included within each particular SOP section, along with writing dos and don'ts.

SOP describes methods in ozone therapy that should be included:

1. Title
 - 1.1. Brief background
 - 1.2. Purpose
 - 1.3. Scope
 - 1.4. Acronyms, abbreviations and definitions
2. Responsibility
3. Procedure
 - 3.1 Indications
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 - 3.3 Recommended doses intervals
 - 3.4 Clinical evaluation
 - 3.5 Preliminary operations
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References:

URL: <http://hub.ucsf.edu/sop-guidelines>

Change History

SOP no.	Effective Date	Significant Changes	Previous SOP no.
ISCO3/QAU/00/12	05/09/2015	First version approved by ISCO3 Board	First version

Document Records

	Name	Title	Signature	Date
Author	Gregorio Martínez-Sánchez	Elected president Ph.D.; Pharm. D.		31/08/2015
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Authoriser / Approved	ISCO3 Board 2015-2020			



Attachment 1. Hypothetic example of SOP Clinical Method

Note: The following is a hypothetic example of a procedure. This is not a draft under review.

1. Title ISCO3/MET/00/17 Intratonsillar infiltration route

1.1. Brief background

Tonsillar diseases are among the most commonly encountered health-related problems in the general population. The choice of treatment is often tonsillectomy, which is still the most frequently performed surgical procedure in children and young adults. Although chronic tonsillitis are still the most common reasons for tonsillectomy.¹ Ozone infiltration can quickly improve the inflammatory an infection status of the tonsilla.²

1.2. Purpose

The purpose of this SOP is to describe the procedure to conduct the intratonsillar infiltration of ozone.

1.3. Scope

This procedure specified the infiltration technique, doses, volume of gas and frequency of application of ozone in tonsil diseases. The concomitant use of ozonized oil, hydrosol of ozonized or ozonized water in tonsillitis is not described in this SOP.

1.4. Acronyms, abbreviations and definitions

SOP	Standard Operation Procedure
Tonsils	Are collections of lymphoid tissue facing into the aero-digestive tract. The set of lymphatic tissue known as Waldeyer's tonsillar ring includes the adenoid tonsil, two tubal tonsils, two palatine tonsils, and the lingual tonsil. ³

2. Responsibility

Physician	Clinical records registration Assessment of the indication, contraindications Request the informed consent and the privacy consent Applications and monitoring Recording all data on medical records Prescription of investigations to assess the effectiveness of the treatment (e.g. microbiology) Reporting any late complications Patient follow-up
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Nurses	Accommodate the patients Preparation of the clinical procedure Supervision of patients, and vital signs control (temperature and pressure) Detects and alerts the doctor to anomalies due to possible reactions Notification of possible complications
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3. Procedure

3.1 Indications

This is a secure route in patients older than 12 years old, on condition that they can actively cooperate when they are asked to hold their breath (apnea) while the medical ozone injection is applied. Can be used also in nasal polyp. (ISCO3/QAU/01/03)

3.2 Contraindications

Patients that can 'not actively cooperate.

3.3 Recommended doses intervals

Concentrations of (10 - 20) $\mu\text{gN/mL}$ with a volume of 2.5 mL per point to infiltrate at the anterior and rear pillar of both tonsils are used. Four to five sessions are required. In case of nasal polyp, infiltrate directly into the polyp tissue a volume of 2.0 mL at a concentration of 50 $\mu\text{gN/mL}$.⁴ (ISCO3/QAU/01/03)

3.4 Preliminary operations

The practitioner will be well trained in this method.

Fill all medical records of the patient, get the informed consent (ISCO3/QAU/00/21) and the privacy consent.

Make the appropriate diagnose and verify the indication and contraindication.

Prepare the appropriate dose of ozone using and adequate device ISCO3/DEV/00/01.

3.5 Clinical evaluation

Using a tongue depressor and appropriate medical lamp and magnifying glass, check the tonsil

3.6 Main procedure

- 1) Ask to the patient to hold the breath (apnea) and open the mouth.
- 2) Use a tongue depressor, and a medical lamp to visualize the tonsil
- 3) Infiltrate at the anterior and rear pillar of both tonsils (if is the case) with ozone.
Concentrations of (10 - 20) $\mu\text{gN/mL}$ with a volume of 2.5 mL use a needle 27 G (0.4) or 30 G (0.3 mm) x 1 1/2 (40 mm).
- 4) Ask the patient to do an forced expiration.⁵



3.7 Alternatives

Using for application a Canula (**Canula sinus maxilar Hartmann**, ORL inox Japonia, Raydent: Ø 2 mm. Ø 2,5 mm. Ø 3 mm) in place of local injection.⁵ Forced expiration is required in this method.

3.8 Frequent side effects

Local pain.

3.9 Patients Follow-up

Check the patients ones a week.

4. Contingencies; Corrective Actions

In case of incidental O₃ inhalation follow procedure ISCO3/CLI/00/01.

5. References

5.1 SOP References

ISCO3/DEV/00/01 Guidelines and Recommendations for Medical Professionals Planning to Acquire a Medical Ozone Generator.

ISCO3/QAU/01/03. Madrid Declaration on Ozone Therapy 2015-2020 Eng. Schwartz-Tapia A, Martínez-Sánchez G, Sabah F, Alvarado-Guómez F, Bazzano-Mastrelli N, Bikina O, Borroto-Rodríguez V, Cakir R, Clavo B, González-Sánchez E, Grechkanev G, Najm Dawood A H, Izzo A, Konrad H, Masini M, Peretiagyn S, Pereyra, V R, Ruiz Reyes D, Shallenberger F, Vongay V, Xirezhati A, Quintero-Marino, R. **Madrid Declaration on Ozone Therapy**. 2th ed. Madrid: ISCO3; ISBN 978-84-606-8312-4; 2015. 50 p.

ISCO3/QAU/00/21. Informed Consent Form in Ozone Therapy.

ISCO3/CLI/00/01. Fist Aids in ozone therapy (Inhalatory exposition and accidental over dose)

5.2 Other References

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6. Documentation and Attachments

6.1 List of recommended medical disposables

Needle 27 G (0.4) or 30 G (0.3 mm) x 1 1/2 (40 mm).
Siliconated Luer lock syringe of 5 mL
Tongue depressor

7. Change History

SOP no.	Effective Date	Significant Changes	Previous SOP no.
ISCO3/MET/00/17	1/09/2015	Draft. Especial edition as methodological example	First version

8. Document Records

	Name	Title	Signature	Date
Author	Gregorio Martínez-Sánchez	Elected president Ph.D.; Pharm. D.		1/09/2015
Co. Authors / Reviewer	Fadi Sabbah	Elected vice- president D.DS.		xx/09/2015
	Adriana Schwartz	Elected secretary M.D.		xx/09/2015
Authoriser / Approved	ISCO3 2015-2020 All members.			