Title ISCO3/CLI/00/25 Psoriasis

Index

1. Title ISCO3/CLI/00/25 Psoriasis

1.1. Brief background

Psoriasis is a complex immune-mediated inflammatory disease that occurs in genetically susceptible individuals and presents with the development of inflammatory plaques on the skin. Although early concepts of psoriasis pathogenesis focused primarily on keratinocyte hyperproliferation, dysregulation of the immune system is now recognized as a critical event in the disease.[1] The evolving knowledge of the role of the immune system in psoriasis has had a significant impact on treatment development. Many new and emerging therapeutic agents target specific immunologic aspects of psoriatic disease.

The estimates of the prevalence of psoriasis in adults ranged from 0.51 % to 11.43 %, and in children from 0 % to 1.37 %. Psoriasis is a common disease, occurring more frequently with advancing age. Limited data on the epidemiology of psoriasis are available. The available prevalence data come from only 20 countries, meaning there are huge geographic gaps in knowledge, especially from low- and middle-income settings.[2]

1.2. Purpose

The purpose of this SOP is to describe the procedure for treating with ozone.

1.3. Scope

This procedure specified the diagnosis, anatomical main aspects, technique, doses, volume of gas and frequency of application of ozone in psoriasis.

1.4. Acronyms, abbreviations and definitions

b.w.	Body weight
MAH	Major Autohemotherapy
MiAH	Minor Autohemotherapy
PASI	Psoriasis Area and Severity Index, score
SOP	Standard Operating Procedure

2. Responsibility

Physician

Clinical records registration.
Assessment of the indication, and contraindications.
Request the informed consent and the privacy consent.
Applications and monitoring.
Recording all data in medical records.
Prescription of investigations to assess the effectiveness of the treatment (e.g. microbiology).
Reporting any late complications.
Patient follow-up.

Nurses

Accommodate the patients.
Preparation of the equipment and materials for the clinical procedure.
Supervision of patients and vital signs control (temperature and pressure).
Detects and alerts the doctor to anomalies possible reactions.
Notification of possible complications.

3. Epidemiology

Estimates of psoriasis prevalence have varied across studies. A systematic review of international population-based studies found wide variation in psoriasis prevalence worldwide.[3] The prevalence of psoriasis in adults ranged from 0.91 to 8.5 percent,[4] and the prevalence of the disease in children ranged from 0 to 2.1 percent. Geographic location appeared to influence the likelihood of having psoriasis; disease prevalence tended to increase with increasing distance from the equator.[3]

There is not a clear gender predilection for psoriasis.[5] Although psoriasis can begin at any age, the disease is less common in children than adults.[6] There seem to be two peaks for the age of onset: one between the ages of 30 and 39 years and another between the ages of 50 and 69 years.[4,5]

The incidence of psoriasis may be increasing. A retrospective study of a cohort of adults reported an increased incidence of psoriasis between 1970 and 1974 (50.8 cases per 100,000) and 1995 and 1999 (100.5 cases per 100,000).[4] Another cohort study assessing the incidence of psoriasis in children also reported an increasing incidence, from 29.6 cases per 100,000 to 62.7 cases per 100,000 during the same time periods.[6] However, few other studies report on incidence to confirm these findings. Changes in diagnostic patterns over time also may contribute to increasing rates of diagnosis.

4. Etiology

Psoriasis has a multifactorial etiology. Apart from the genetic proneness, risk factors that trigger psoriasis include trauma, infection, metabolic factors, stress, alcohol, smoking, and sunlight. Besides these factors, there are also some medications that can exacerbate this disease, including: antimalarials, beta blockers, bupropion, calcium channel blockers, captopril, fluoxetine, glyburide, granulocyte colony-stimulating factor, interferon, interleukins, lipid-lowering drugs, lithium, penicillin, and terbinafine.[7]

5. Pathophysiology

Psoriasis is caused by inappropriate activation of the immune system defined by a series of linked cellular changes in the skin that include keratinocyte hyperplasia; altered T cell function and angiogenesis, the most important cell series being the helper T cells. The role of oxidative stress, reactive oxygen species [ROS], and an increased expression of insulin-like growth factor-1 (IGF-1) and epidermal growth factor (EGF) in the pathogenesis of psoriasis has been proven. Many psoriasis susceptibility loci have been detected by linkage studies (PSORS1-12). HLA-Cw6 allele has a strong association with early-onset psoriasis.[8]

6. Diagnosis Consideration

Psoriasis has to be differentiated from other close mimickers like tinea corporis [ringworm disease] and eczema and in some cases, both can coexist. Epidermal nevus should be differentiated from Blaschko's linear psoriasis. In chronic plaques that resist treatment, Bowen's disease and cutaneous T-cell lymphoma should be excluded by histological examination.[9,]

Diagnosis of plaque psoriasis is essentially clinical. Dermoscopy is an easy way to make a diagnosis, which shows dotted vessels in a regular arrangement over a light red background and white scales. A biopsy is done to differentiate from close mimickers. The classical histological findings vary according to the stage of evolution. Histology of a well-developed plaque shows compact orthokeratosis, parakeratosis, spongiform pustule, micro-abscess with neutrophil collection in the upper epidermis, acanthosis, elongation of rete with the widening of the bases, supra-papillary thinning, and tortuous dilated papillary capillaries. Dilated capillaries and keratinocyte proliferation are the consistent features in all stages of psoriasis. It is mandatory to screen all patients with moderate to severe psoriasis for metabolic comorbidities like obesity, hypertension, diabetes, and dyslipidemia.[10]

More research is being conducted, in the arena of biomarkers in psoriasis. Leptin and resistin are considered candidate biomarkers for prediction of development of insulin resistance and atherosclerosis in obese patients with psoriasis. K16 expression in non-lesional psoriatic epidermis has been suggested as a marker of preclinical psoriasis. IL-18 is the candidate cytokine biomarker of disease severity. Lower levels of cell surface expression markers of T-cell subsets, such as CD8, CD45RO, CD2, CD94, and CD161 are features of ILVEN but not in the case of Blaschko linear psoriasis.[11]

7. Conventional Treatment / Management

Treatments must be tailored to suit the age of the patient, quality of life [QOL] issues, and PASI Score. Treatment can be broadly categorized as topical applications, phototherapy, systemic drugs, and other modalities. The topical therapy includes emollients & moisturizers, fish oil, corticosteroids, keratolytics, tar, anthralin, vitamin D3 analogs, calcineurin inhibitors, cyclosporine in a liposomal formulation, retinoids, and newer drugs. The combination of topical agents sometimes is more effective than when the drugs are used alone. Neuropeptide-modulating agents, newer NSAIDs like WBI-1001, LAS41002, and LAS41004, Janus-associated Kinase Inhibitors, MEK1/MEKK1 Inhibitor, Phosphodiesterase Inhibitors, Pan-selectin antagonists, fibroblast growth factor 23 [FGF 23], are newer topical drugs under research. The common sources of light therapy used in the management of plaque psoriasis include UVB [Broad & narrow band] Photo chemotherapy with UVA-Psoralen with UVA [PUVA], combined therapy including home phototherapy4 and the LASER.[9]

Systemic drugs used include retinoid, methotrexate, cyclosporine, tacrolimus, hydroxyurea, 6-thioguanine, azathioprine, fumaric acid esters and biologic agents. Of the available biologic agents, Etanercept, adalimumab, infliximab, secukinumab, ustekinumab, ixekizumab, apremilast are indicated for plaque psoriasis of which etanercept can be safely used in children with proper monitoring. Other treatment modalities like fish oil rich in omega-3 fatty acids, are a good dietary supplement.

Extra care must be taken while treating a pregnant woman with psoriasis in whom UVB can be safely used, and the risk of topical PUVA is considered low in pregnancy. Adalimumab, etanercept, and infliximab come under FDA category B, anthralin, betamethasone dipropionate, calcineurin inhibitors, cyclosporine, psoralen, methylprednisolone aceptonate are category C drugs whereas acitretin, methotrexate; tazarotene belong to Category X.

Since psoriasis is a chronic inflammatory disease with remissions and exacerbations, often requiring prolonged therapy the choice of therapy should be made, taking into consideration the long-term side effects of therapy with particular reference to topical steroids and other immune-suppressive agents. High-potency topical steroids like clobetasol propionate are contraindicated in young children for fear of side effects like atrophy, depigmentation, and precipitation of pustular psoriasis on sudden withdrawal. While using phototherapy and systemic drugs, similar caution should be exercised. In children the immature hepatic, renal systems and active hematopoietic system make it even more difficult to handle systemic drugs. Since the long-term side effects of newer drugs are not available to date, it is prudent to use them only when indicated. The role of alefacept in HIV-associated psoriasis is being considered.[12,13]

8. Evidence of ozone effect

Level of evidence: Level C, according to the definition of ISCO3. Madrid Declaration on Ozone Therapy, 4th ed., 2025. Madrid. www. isco3.org.

Evidence: Some clinical trial demonstrated the adjuvant effect of ozone therapy in psoriasis.[13-17] The immune modulation that take place during ozone therapy may support the improvement of

the patient treated with ozone. The prevalent way of administration is the minor authohemo therapy.[15] Krivatki and Krivatkina (1998) observe clinical improvement in 60 % of treated patients. Glavinskaia *et al.* (2003)[18] treated 145 patients and got a 66 % improvement that increased to 85% when ozone was combined with local 8-hydroxyquinolina and calcitriol (1,25-dihydroxycholecalciferol or 1,25-dihydroxyvitamin D_3). Ozonized oil by ingestion was also associated with an improvement of clinical signs of psoriasis.

9.0 Procedure

9.1 Indications

Plaque psoriasis, included other forms of psoriasis, such as guttate and pustular.

9.2 Contraindications

Patients that have any of the contraindications to ozone therapy (Madrid Declaration on Ozone Therapy, 4th ed., 2025. Madrid.).

9.3 Recommended protocol, and doses intervals

To choose a systemic ozone therapy procedure for psoriasis, we recommend using the PASI scale.
The PASI (Psoriasis Area and Severity Index) score measures the severity of psoriasis, combining the extent of psoriasis, combining the severity of the lesions and the affected area into a single number from 0 to 72. To obtain this score, the body is divided into four sections (trunk, lower limbs, upper limbs, and head), each assessed for erythema, scaling, and induration on a scale of 0 to 6, and the scores are combined into a final score.
Psoriasis is considered mild when it affects less than 3% of the skin surface, moderate when it affects between 3 and 8%, and severe when it affects more than 10%. This scoring system greatly facilitates evaluation and monitoring.
Vitamin D deficiency is common in patients with psoriasis; therefore, consider Vitamin D testing and supplement according to the results.

Systemic procedures:[19]

Minor Autohemotherapy (MiAH) is considered a basic treatment when it affects less than 3% of the skin surface. Follow the procedure ISCO3 SOP/MET/00/02. Blood volume: 5 mL, Ozone concentration: increase the concentration from 20 µg/mL to 45 µg/mL in those steps: (20 to 45) µg/mL Apply every 2 days for 2 weeks, then two times a week per two weeks, one time a week per 1 month, and maintain 1 application every 3 months.

Rectal insufflation: In the case of moderate psoriasis, when it affects between 3 and 8%, apply ISCO3 SOP/MET/00/01, Rectal insufflation. Every two days, 15 sessions, ozone concentration will be *in crescendo* (1 session 25 µg/NmL – 100 mL of ozone; 2 sessions 30 µg/NmL – 120 mL of ozone; 3 sessions 35 µg/NmL – 150 mL of ozone; 4 sessions 40 µg/NmL – 200 mL of

ozone).

Major authohemotherapy: in cases with severe exacerbations Major authohemotherapy (MAH) should be applied. ISCO3.SCO3/MET/00/01 Major Autohemotherapy. Two times a week, 10-12 sessions, ozone concentration will be *in crescendo* (One session at 25 µg/NmL – 100 mL of ozone/blood; Two sessions at 25 µg/NmL – 125 mL of ozone/blood; Three sessions at 30 µg/NmL – 125 mL of ozone/blood; Four sessions at 35 µg/mL – 125 mL of ozone/blood; Two sessions at 40 µg/mL – 125 mL of ozone/blood).

Ozonized saline solution:[20] In the case of severe psoriasis, when it affects more than 10% of the body surface, apply the O_3SS. The formula to apply is: **NaCL 0.154 M= 0.9% pH 5.5-5.7 + O3 1-5 µg/kg, flow rate 100/200 mL/min, 15 min**

The ozone concentration used will be b.w.

Medium Dose 3 µg/kg in 250 mL Twice a week, during 3 weeks
A patient weighing 80 kg will receive: 80 x 3 = 240 µg Total concentration.
240 µg x (1 L/0.25 L= 4) 4 x 240 = 960 mg/L Concentration in the bottle.
960 mg/L x 4 = 3840/1000 = 3.84 µg/NmL Saturation concentration (ozone generator output).
3.84 µg/NmL/4= 0.96 µg/NmL Dose that the patient receives.

Medium/High Dose 4 µg/kg in 250 mL Once a week for 4 weeks.
A patient weighing 80 kg will receive: 80 x 4 = 320 µg Total concentration.
320 µg x (1 L/0.25 L= 4) 4 x 320 = 1280 mg/L Concentration in the bottle.
1280 mg/L x 4 = 5100/1000 = 5.1 µg/NmL Saturation concentration (ozone generator output).
5.1 µg/NmL/4= 1.2 µg/NmL Dose that the patient receives.

*Using the nano/microbubbling method with the ASSO3® device which is the safest and most effective method for this type of procedure and the ozonation time is only 5 minutes. The concentration of ozone is maintained for more than a week in the aqueous medium.

Local treatment: Intra-lesion infiltration, Ozone bags or cup, Ozone sauna, local ozonized oil, ozonized water. (ISCO3 Madrid Declaration on Ozone Therapy, 4th ed., 2025. Madrid. Eng.: ISCO3; ISBN: 978-84-09-72147-4).

Intra-lesional treatment: Use needle 27 G 3/4 (0.41 mm x 19 mm), ozone concentration (2-3) µg/NmL, volume of ozone (0.5 -1.0) mL, applied once a week until remission.[16]

Ozone bags or cup: ozone concentration, increase from (5-10) µg/NmL, time of exposition 20 min, twice a week until remission.

Ozone sauna:[21] ozone concentration 5 µg/NmL, temperature 40 ºC, total time of exposure 20 min, time of ozone exposure 10 min, once a week until remission.

Ozonized oil:[22-26] apply ozonized oil IP 800-1200 twice a day until remission.

Ozonized water: Volume of bi-distilled/distilled H_2O 250 mL, Bubbling time 10-15 min, O_3 concentration 40-60 µg/mL, O_3 flow 10 L/h. Should be applied immediately after preparation, twice a week until remission. Using the nano/microbubbling method with the ASSO3® device, the water only needs to be ozonized for 5 minutes and the concentration in the water is maintained for more than a week under refrigeration in an amber bottle at 8ºC.

Oral treatment: ozonized oil. Ozonized oil: ozonized oil 600 IP, 2 g, 3 times a day on an empty stomach, of for 14 days.

9.4 Preliminary operations

The practitioner must be well-trained in this method.
Complete all medical records of the patient, obtain the informed consent (ISCO3/QAU/00/21) and the privacy consent.
Make the appropriate diagnosis and verify the indications and contraindications.
Choose the appropriate protocol to fit to the severity of the disease, affected area and patient's conditions.
Prepare the appropriate dose of ozone using an adequate device ISCO3/DEV/00/01. Ask to the patient to indicate the affected area.
Clean the area with an antiseptic solution or ozonized water

9.5 Clinical evaluation

To follow the clinical response, the use of the PASI index is suggested..

9.6 Main procedure

Follow the appropriate protocols for local, oral, or systemic therapy.
Administer oral therapy according to the adequate protocol.
Prevent at least one MiAH for cases in which remission has been achieved, it is suggested to perform ozone therapy to prevent relapses. One MiAH every 3 months is recommended. In cases with relapse, perform the whole cycle of ozone therapy every 4-6 months.

9.7 Alternatives

Ozone therapy may potentiate the effect of regular therapy. For example, the combination with local 8-hydroxyquinolina and calcitriol (1,25-dihydroxycholecalciferol or 1,25-dihydroxyvitamin D_3) increases the therapeutic success by 85 % of patients .[13] In addition, natural treatments can be combined: Glutathione, vit D, homeotherapy, or oligo elements, diet (reduce consumption the of milk, sugar and gluten). Occasionally for severe exacerbations, pharmaceutical medications may be combined with ozone, including: corticosteroids, antihistamines, and immunosuppressants. In general, the use of retinoids and phototherapy is not necessary.

9.8 Potential side effects

Local pain is expected with the use of needles for intralesional, intramuscular, or intravenous injection.
One case of fatal death was reported during the application of MAH in a patient with psoriasis.[27] It is assumed that was due to highly inappropriate administration. MAH has been demonstrated to be a safe method of ozone administration.
Events of side effects may be reported using: ISCO3/REC/00/03 The ISCO3 Safety Information

and Adverse Event Reporting Program Form.

9.9 Patients Follow-up

Check the patients weekly during the acute phase, and every 3 months during remission.

10. Contingencies; Corrective Actions

In case of accidental O_3 inhalation follow procedure ISCO3/CLI/00/01.

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12.0 Documentation and Attachments

12.1 List of recommended medical disposables

Needle 27 G (0.4) or 30 G (0.3 mm) x 3/4 (19 mm).
Siliconized Luer lock syringe of 5 mL
Ozonized oil 800-1200 IP
ASSO3® device for O_3SS
Bottle with citrate for MAH
Silicone cannula for Rectal Insufflation (RIO_3)

12.2 Proposal of Informed concent

Informed Consent Form in Ozone Therapy in the treatment of psoriasis

Mr./Miss. Surname: Name:

Place of Birth: Date of Birth (dd/mm/yy): / /

Resident

Identity Number Phone

Health care center:

a) Pathology: psoriasis

b) Therapeutic alternatives related to the symptoms presented by the patient: topical applications, phototherapy, systemic drugs and other modalities.

c) Medical or surgical treatment that you will apply (explain why and what you want to achieve): systemic and local treatment with ozone, to modulate the immune system and to reduce the skin lesion.

d) Procedure before applying the primary treatment: clean the affected area.

e) Main Procedure (what will be done and how long): Systemic (rectal, vaginal, intravenous or intramuscular), Local application (sauna, bag, local injection, oil) or oral (ozonized oil or ozonized water) to complete a cycle of treatment.

f) Possible treatments or interventions that may be necessary in addition to the main treatment: first aid in case of an incident

g) Complications: local reaction to ozone gas, erythema or local pain for a few minutes

h) Adverse effects that may manifest after therapy: low local pain.

i) Therapy or directions you need to follow after the main intervention: follow-up once a week during relapses and every three months during remission.

The undersigned (taking into consideration as described above, with full awareness and freedom)

DECLARES

- ✓ Be fully aware,
- ✓ Having carefully read the entire document,
- ✓ That the doctor who carried out the treatment has explained everything to my full understanding of what has been stated in the document,
- ✓ To have fully understood the content of the document,
- ✓ Authorize the executor doctor to make the surgical/medical treatment described above,
- ✓ I can stop treatment at any time,
- ✓ What can be compensated as a result of the procedure if unforeseen or unexpected injuries were originate,
- ✓ Authorize from this moment the procedure described in item f).

Date (dd/mm/yy) / / Patient signature*

* Representative or guardian (if the patient does not cooperate or is a minor).

Declaration of the physician in charge to inform the patient.

The undersigned Dr. confirms and attests, by signing this document, that it, in my opinion, has been understood in full, point by point, by the patient.

Date (dd/mm/yy) / / Physician signature*

* All previously reported herein provides a synthetic information about the procedure and its function does not replace the doctor / patient dialogue.

13.0 Change History

SOP no.	Effective Date	Significant Changes	Previous SOP no.
ISCO3/CLI/00/25	30/ 10/25	Draft. Under Revision by Expert	First version
ISCO3/CLI/00/25	17/11/ 2025	Draft. Under Revision by Expert	Second version

14.0 Document Records

	Name	**Title**	**Signature**	**Date**
Author	Schwartz Adriana	M.D. Gynecologist. President of ISCO3		30/10/25
Reviewer working group	Dr. Sergey Peretiagyn	M.D.Traumatologist Professor, member of the Russian Academy of Medical Sciences.		
	Dr. Bernardino Clavo	M.D. PhD Cum Laude. Oncologist.		
	Dr. Wayne McCarthy	ND. Integrative Medicine.		
	Dr. Ana Gossweiler	DDS, ND, Periodontology. Research Associate Professor, Indiana University.		
	Dr. Valerie Davis	MD. Dermatology.		

Approved: November 11th 2025 by ISCO3 members.