ISCO3/MET/00/18

Ozone micro doses in reflexology, acupuncture and trigger and points

Index

Title: ISCO3/MET/00/18. Ozone micro doses in trigger and acupuncture points ................. 2
1.1 Brief background ........................................................................................................... 2
1.2. Purpose ...................................................................................................................... 2
1.3. Scope ......................................................................................................................... 2
1.4. Acronyms, abbreviations and definitions ................................................................. 2
2. Responsibility .............................................................................................................. 3
3. Procedure ...................................................................................................................... 3
3.1 Indications .................................................................................................................. 3
3.2 Contraindications ....................................................................................................... 4
3.3 Recommended doses and intervals ............................................................................. 4
3.4 Clinical evaluation ...................................................................................................... 4
3.5 Preliminary operations ............................................................................................... 4
3.6 Main procedure ......................................................................................................... 4
3.7 Side effects ................................................................................................................ 5
3.8 Patients Follow-up ..................................................................................................... 5
3.9 Effect Mechanism ...................................................................................................... 5
4. Contingencies; Corrective Actions ............................................................................. 5
5. References .................................................................................................................. 5
5.1 SOP References ......................................................................................................... 5
5.2 Other References ....................................................................................................... 6
6. Documentation and Attachments ................................................................................ 6
6.1 List of recommended medical disposables ................................................................... 6
7. Change History ........................................................................................................... 6
8. Document Records ..................................................................................................... 7
Title: ISCO3/MET/00/18. Ozone micro doses in reflexology, acupuncture and trigger and points

1.1 Brief background
One of the application routes of ozone-oxygen therapy is the intradermal, subcutaneous, or intra-muscular route. In this capacity ozone-oxygen produces lipoperoxides which produce metabolic stimulation, analgesia, and anti-inflammatory effects in both soft tissues and in nervous tissue. Injection of substances in acupuncture points is common with the aim of reinforcing the acupuncture effect, using for example: sodium chloride solution, sterile water, vitamins, procaine 1 %, plant-based drugs, homeopathic remedies or conventional medicines. When injected into trigger points ozone-oxygen expands and disrupts tissue and fascia and thus has the potential to correct the trigger point pathology.

1.2. Purpose
The purpose of this SOP is to describe the procedure for the use of ozone injected into acupuncture, reflexology and trigger points.

1.3. Scope
This procedure specifies the volume, concentration and frequency of ozone injection into acupuncture, reflexology areas and trigger points.

1.4. Acronyms, abbreviations and definitions

<table>
<thead>
<tr>
<th>SOP</th>
<th>Standard Operation Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture</td>
<td>Is a form of Chinese medicine that can be traced back at least 2 500 years. The general premise of acupuncture is that the body contains patterns of energy flow. The <em>vital energy</em> or <em>life force</em> of the body is referred to as <em>qi</em> (pronounced &quot;chee&quot;), and proper flow of <em>qi</em> is considered to be necessary to maintain health.</td>
</tr>
<tr>
<td>Reflexology</td>
<td>Is a therapeutic approach involving application of pressure to the feet and hands with specific thumb, finger, and hand techniques without the use of oil or lotion. It is based on a system of zones and reflex areas that purportedly reflect an image of the body on the feet and hands, with the premise that such work effects a physical change to the body.</td>
</tr>
<tr>
<td>Trigger point</td>
<td>Is a sensitive area in the muscle or connective tissue (fascia) that becomes painful when compressed.</td>
</tr>
</tbody>
</table>
2. Responsibility

Physician
Patients’ Clinical records registration (ISCO3/REC/00/02)
Assessment of the indication, contraindications
Request the informed consent (ISCO3/QAU/00/21) and the privacy consent
Applications and monitoring
Prescription of investigations to assess the effectiveness of the treatment (e.g. pain scale or disability index, etc.)
Reporting any late complications (ISCO3/REC/00/03)
Patient follow-up

Nurses
Accommodate the patients
Preparation of the clinical procedure
Supervision of patients, and vital signs control
Detects and alerts the doctor to anomalies due to possible reactions
Notification of possible complications

Physicians need special training in acupuncture methods or to detect trigger points and reflexology areas.

3. Procedure

Acupuncture points: Ozone-oxygen is injected intradermally or subcutaneously into each acupuncture point. This can be repeated as per traditional acupuncture protocols.

Trigger points: Ozone-oxygen is injected intramuscularly into each trigger point. This can be combined with traditional trigger point therapy using cryotherapy, local anesthetic, and steroid injection.

3.1 Indications

Acupuncture therapy - ozone-oxygen has been used in traditional acupuncture protocols for localized pain relief and for systemic autonomic balancing.

Trigger point therapy is primarily a pain reducing therapy. Trigger points are commonly found in and around painful areas. Those are hyperirritable spots in the fascia surrounding skeletal muscle. They are associated with palpable nodules in taut bands of muscle fibers
3.2 Contraindications

Other than standard contraindications for ozone therapy (see ISCO3/QAU/01/03) or either acupuncture or trigger point therapy there are no specific contraindications to the use of ozone-oxygen in these applications.

3.3 Recommended doses and intervals

Acupuncture points: (0.3-1.0) mL of ozone-oxygen is injected intradermally or subcutaneously at (6-9) µgN/mL into each acupuncture point. This can be repeated as per traditional acupuncture protocols. (ISCO3/QAU/01/03).

Trigger points: they are located in the muscles and are often deep, so the application has to be intramuscular and the volume can be between (3-5) mL at concentration between (10-20) µg/NmL into each trigger point. This can be repeated twice a week as needed and can be combined with traditional cryotherapy, local anesthetic (procaine 1%) or local steroid injection (ISCO3/QAU/01/03).

3.4 Clinical evaluation

A clinical and/or laboratory evaluation is necessary to establish a precise diagnosis and to permit comparisons between the patient’s status before, during, and after treatment.

3.5 Preliminary operations

As per traditional acupuncture and trigger point therapy. As many points as necessary can be injected with ozone-oxygen. Generally, not more than 8 points should be injected at once. In case of foot point, apply dry ice or chloretilo in the site of injection, just before the ozone application.

Acupuncture: identified the point to be treated.
Trigger points: identified the triggers points.

Use only medical grade oxygen and Medical Grade Generator (ISCO3/DEV/00/01).

3.6 Main procedure

Clean and disinfect the area first, then proceed to infiltrate slowly, aspirating time to time to avoid the pass of the gas to any vascular vessel
3.7 Side effects

When concentrations above 9 µgN/mL are used there will be some local irritation and pain. Concentrations above 15 µgN/mL are particularly painful. As with all injection therapies due to the possibility of infection standard antiseptic procedures should always be employed. No other side effects are noticed.

3.8 Patients Follow-up

Patients may be followed and re-evaluated as per traditional acupuncture, reflexology and trigger point therapy.

3.9 Effect Mechanism

When introduced into tissue ozone immediately reacts with lipids to form lipid peroxides. These peroxides can persist in the tissue for days to weeks. The ozone thought its mediators acts locally without any systemic implication and:
1. Stimulate vasodilatation increasing local circulation
2. Stimulate oxidative processes such as metabolism, antioxidant enzyme synthesis, and NAD (nicotinamide adenine dinucleotide) activation.
3. Produce an analgesic effect through the activation of the descending anti-nociceptive system.
4. Release endorphins which block transmission of the noxious signal to the thalamus and cortex.
5. Elevate the pain activation threshold through the oxidative inactivation of C-nociceptors.
6. Decrease edema and inflammation.

4. Contingencies; Corrective Actions

As with any injection procedure a vasovagal response is possible. Patients should be well hydrated and fed before each procedure to avoid this complication. As a precaution always inject slowly.

5. References

5.1 SOP References

ISCO3/DEV/00/01 Guidelines and Recommendations for Medical Professionals Planning to Acquire a Medical Ozone Generator.
ISCO3/CLI/00/01. Fist Aids in ozone therapy (Inhalatory exposition and accidental over dose)
ISCO3/REC/00/02 The ISCO3 Recommended Patients form
ISO3/REC/00/03 The ISO3 Safety Information and Adverse Event Reporting Program Form.

5.2 Other References


6. Documentation and Attachments

6.1 List of recommended medical disposables

Gloves
30 G x 1/4" needles
7. Change History

<table>
<thead>
<tr>
<th>SOP no.</th>
<th>Effective Date</th>
<th>Significant Changes</th>
<th>Previous SOP no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISCO3/MET/00/18</td>
<td>16/06/2016</td>
<td>First version draft under revision</td>
<td>First version</td>
</tr>
<tr>
<td></td>
<td>27/08/2016</td>
<td>Version 1. Final version</td>
<td></td>
</tr>
</tbody>
</table>

8. Document Records

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Author</strong></td>
<td>Frank Shallenberger</td>
<td><a href="mailto:doctor@antiagingmedicine.com">doctor@antiagingmedicine.com</a></td>
<td>MD., Member ISCO3</td>
</tr>
<tr>
<td><strong>Co. Authors / Reviewer</strong></td>
<td>Gregorio Martínez-Sánchez</td>
<td>Ph.D. ISCO3 President 2015-2020</td>
<td>13/06/2016</td>
</tr>
<tr>
<td><strong>Reviewer</strong></td>
<td>Dr. Adriana Schwartz-Tapia</td>
<td>MD., Gynecologist Member of ISCO3 Board</td>
<td>27/08/2016</td>
</tr>
<tr>
<td><strong>Authorizer / Approved</strong></td>
<td>ISCO3 Board 2015-2020</td>
<td></td>
<td>27/08/2016</td>
</tr>
</tbody>
</table>