

ASPS Guiding Principles for Mesotherapy/Injection Lipolysis

The terms “mesotherapy” and “injection lipolysis” are often used interchangeably. While somewhat different, both therapies are advertised as a non-surgical alternative to liposuction. As the promotion and popularity of mesotherapy and injection lipolysis has increased, so too has the controversy surrounding their use. Questions regarding the safety and efficacy of these therapies and whether or not their use is in violation of federal or state regulations abound. Before pursuing mesotherapy or injection lipolysis use in a practice, plastic surgeons should be aware of, and carefully consider, the numerous medico-legal aspects associated with these therapies.

1. Background

Originally developed in Europe, mesotherapy is a general term describing a technique that utilizes a series of injections of pharmaceutical and homeopathic medications, plant extracts, vitamins, and other ingredients into subcutaneous fat. While mesotherapy has been touted for the treatment of a wide variety of ailments, one of its notable indications is for dissolving localized fat accumulations. The term injection lipolysis is used specifically in reference to the practice of injecting various phosphatidylcholine deoxycholate formulations into subcutaneous fat deposits. The injections are generally administered over multiple treatment sessions. There are no standard formulations for either mesotherapy or injection lipolysis.

2. Regulatory Environment

- **Food and Drug Administration (FDA) Approval:** Currently, there is no known FDA-approved injectible solution or pharmaceutical preparation for mesotherapy or injection lipolysis. Thus, physicians who wish to perform this therapy for adipose reduction may be subject to some degree of liability as the FDA may review individual occurrences on a case-by-case basis for enforcement action.
- **Compounding:** The FDA regulates drugs bought and sold in the United States as well as establishes protocols for compounding drugs, the process of mixing drugs by a pharmacist or physician to meet the unique needs of a patient. Phosphatidylcholine and sodium deoxycholate are both FDA approved for uses other than mesotherapy or injection lipolysis. However, the legality of compounding them for the purpose of injection lipolysis is controversial, because combining phosphatidylcholine and sodium deoxycholate would produce a “new drug” that is not approved by the FDA for subcutaneous injections. As part of a statement issued February 1, 2008, the FDA clearly stated that most compounded drugs are not FDA-approved drugs.¹ Physicians pursuing this compounding approach to administer injection lipolysis may be subject to enforcement actions by the FDA if their practices do not meet the criteria outlined in the FDA Compounding Compliance Policy Guide.² In addition, medical providers and pharmacists are bound to adhere to State regulations governing compounding, which are determined by individual state regulatory bodies.
- **Off-label Use:** Compounded drugs should not be confused with the “off-label” use of drugs. FDA approval of a drug indicates use of the drug for a specific purpose. Once a drug is approved by the FDA, a licensed physician may prescribe a drug for uses other than the indicated purpose, provided there is scientific evidence / literature to support such use. However, because the mixture of drugs and other ingredients in mesotherapy formulations produce a new drug that is not FDA approved for any purpose, its use would not be considered “off-label” use.
- **State Regulation:** The FDA shares regulatory authority over the use of drugs with individual states. Both Kansas and Nebraska have taken steps to limit the utilization of mesotherapy by physicians. On March 12, 2008, the Kansas Board of Healing Arts voted to prohibit use of phosphatidylcholine and/or sodium deoxycholate unless part of an FDA-sanctioned clinical trial or an individualized prescription from a compounding pharmacy for a specific patient. The ban also prohibits bulk purchases of the products. On February 19, 2008, the Nebraska Legislature introduced a bill that prohibits the administration of subcutaneous injection of phosphatidylcholine or sodium deoxycholate, or any combination of the substances for the purpose of eliminating or reducing local fat accumulation. Upon its recess in April 2008, the Legislature indefinitely postponed the bill.

3. Scientific Evidence

There is very limited scientific evidence available on mesotherapy or injection lipolysis for fat reduction. A thorough search of the literature found 14 references for mesotherapy for fat reduction or injection lipolysis. Based on a critical appraisal of the relevant literature, the majority of articles were found to be levels IV and V, the lowest levels of validity for scientific studies. Three of the fourteen articles were not rated due to the fact they were too poorly designed; and, were therefore rated to be of low quality.³⁻¹⁵ Furthermore, these studies do not offer comparable information on formulations and dosages of key ingredients, which are two elements necessary to compare safety and efficacy of treatments. The low levels of validity and quality of the literature does not allow ASPS to support a recommendation for the use of mesotherapy/injection lipolysis for fat reduction.

4. Guiding Principles

1. It is the individual physician's responsibility to understand and abide by all applicable Federal, State, and local regulations.
2. Only FDA-approved uses of drugs may be commercially advertised; it is illegal to commercially advertise any non-approved or off-label use.
3. Each physician must ensure that a means for providing the appropriate informed consent for each patient has been established prior to the treatment. The consent should include the fact that there is very limited scientific evidence available to verify the efficacy of mesotherapy and/or injection lipolysis for the treatment of dissolving fat accumulations.
4. Because safety and efficacy cannot be ascertained from the available body of English literature, ASPS believes further scientific testing of fat reduction mixtures is needed before recommendations on their use may be formally issued.
5. Physicians administering mesotherapy treatments should be aware of the chemicals/drugs being injected, dosages, particular side effects, and potential interactions.
6. Records of injected substances and dosages administered should be available in the patient's medical record and accessible to other treating physicians.
7. When interpreting and applying these guiding principles to their individual practice, physicians should use their personal and professional judgment. These guiding principles should not be construed as a rule and are not meant to serve as the standard of medical care.

References

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