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**Editorial**

# The I-GUANA Shot® Protocol for Erectile Dysfunction by Regenerage®

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## Editorial

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Erectile dysfunction (ED) is the persistent inability to achieve or maintain an erection sufficient for satisfactory sexual performance, it can affect men of any age, however age is an important factor that influences the development of ED since estimates suggest that 10% of men under 40 years of age have it but the rate increases to almost 30% in men 50 years and older of 50% in men over 60 years of age, however, more recent studies mention a condition in young people in up to 30%. It is a common disorder that negatively affects the quality of life of men who suffer from it. Its prevalence varies among different countries, cultures, and races [1]. The first published population studies date back to the early 90's and are still valid until today. All reflect the influence that age has on the prevalence of this pathology, as well as its close relationship with cardiovascular diseases. Depending on the definition used and the design of the study, the prevalence varies between 10 and 52%, particularly in men between 40 to 70 years of age, with an incidence of 25-30 new cases per 1000 inhabitants per year in western countries. As mentioned, erectile dysfunction is the inability to attain and maintain an erection with sufficient rigidity to permit satisfactory sexual intercourse [2,3]. While oral pharmacotherapies such as phosphodiesterase-5 inhibitors (PDE5i) exhibit clear benefits, their effects are transient as opposed to an etiological therapy approach and treatment is relatively costly [4-7]. The recent increase in modifiable risk factors for ED, such as obesity and metabolic syndrome, has caused a higher prevalence in recent years and in fact predictive models show a projection of 322 million cases by 2025. The MALES Study (Phase I): Involved 27,839 men between the ages of 20 and 75 from 8 countries (United States, United Kingdom, Germany, France, Italy, Spain, Mexico, and Brazil) [8]. It confirmed the high prevalence rates of erectile dysfunction and its association with medical conditions with significant morbidity and mortality such as diabetes and depression, and that despite the advent of oral phosphodiesterase inhibitors, only 58% of patients with DE consult a doctor about their problem [8-11].


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In a longitudinal study conducted by Johannes et al., the incidence was estimated to be 25.9 cases per 1,000 men, with a higher age-adjusted risk, for men with less education, pelvic lesions, diabetes mellitus (DM), coronary artery disease and hypertension [12,13]. A penile erection is a complex event that requires vascular, neural, endocrine and psychological inputs, as well as the integration of nerve, endothelium and smooth muscle signals; and when this signaling pathway fails, the result is ED [14,15]. Being this a common condition that compromises quality of life, particularly within the aging population. This disease is particularly relevant for those surgically treated for prostate cancer, as prostatectomy can involve traction, thermal, ischemic, and inflammatory lesions on the cavernous nerve. Cavernous nerve injury disrupts the release of nitric oxide from nerve endings in the cavernous arteries and body organs, thereby inhibiting erectile capacity. Therefore, denervation of body after cavernous nerve injury has been associated with changes in smooth muscle and collagen that are likely to exacerbate the condition [16].

Recently, a large number of guided studies have been developed based on these theories on the therapeutic effect of SC, including the regeneration of dysfunctional vascular endothelium, nerve injury and cavernous smooth muscle [17-19].

Stem cells have the ability to either multiply through division of daughter cells or transform into specialized cell types, thus holding the potential for enhanced tissue repair and maintenance of numerical capacity [20]. Experimental and few clinical studies have indicated great potential of stem cell treatments as both a causal and symptomatic approach for the treatment of male erectile dysfunction (ED). The I-GUANA shot protocol is an alternative therapy based on science and medical evidence the effect of a one-time injection of mesenchymal stem-cell derived bioactive scaffold in patients with self-reported ED under certain pathologies. The classification underlies the cells' multi-lineage differentiation properties and distinguishes totipotency, pluripotency, multipotency, and unipotency, in descending order based on differentiation capacities [21]. Cells can be extracted from human tissues including bone marrow, adipose tissue, neonatal teeth, umbilical cord blood, placenta, and Wharton's Jelly, with the two latter preparations being reflected upon in the consecutive analysis [22-24]. Stem cell therapy has been proposed in the management of ED with respect to complete replacement of lost or damaged cells or protection of threatened host cells via immunomodulatory effects, provision of trophic factors or gene delivery [25,26].

Stem cells (SC) have the ability to migrate to damaged or ischemic tissues. Once established in target tissues, they begin to differentiate and proliferate locally. There is evidence that SC, through a paracrine effect, stimulate neighboring cells to regenerate damaged tissue and maintain its integrity. Some authors have shown the activation of the angiogenesis process in damaged tissues as a result of chronic ischemic events [27-29].


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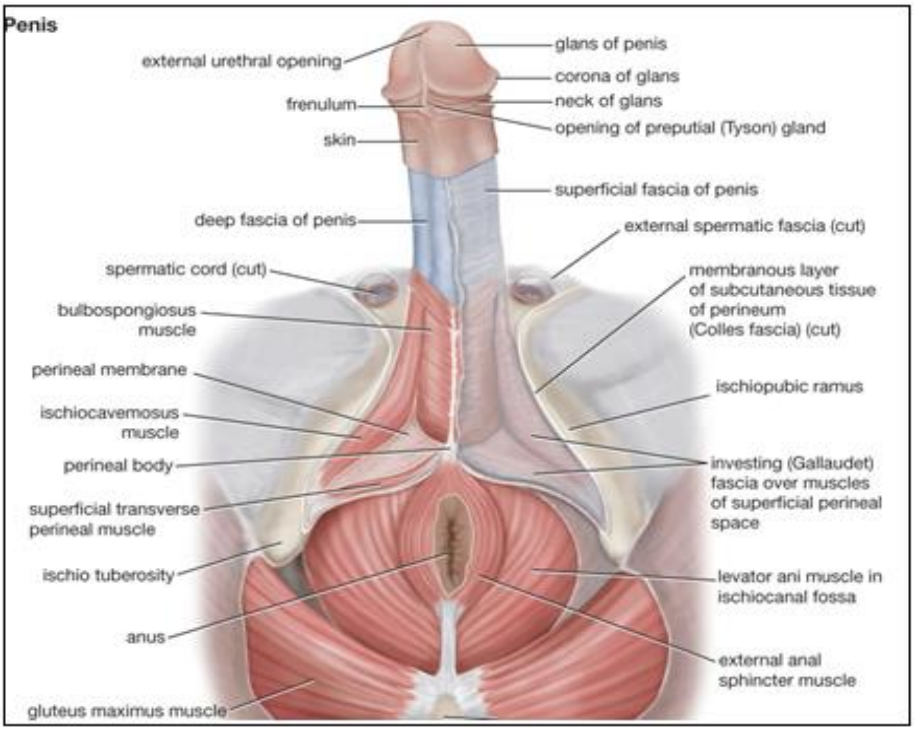


**Figure 1:** Penis anatomy.

## Protocol

A single dose of intra-cavernous application of umbilical cord tissue derivate Mesenchymal Stem Cells scaffold as therapy for Erectile Dysfunction once or twice a year may improve the quality of erection for healthy patients and also for those mentioned under certain clinical conditions.

At REGENERAGE® we use our state of the art BioActivated Mesenchymal Stem Cells (expanded and cultured with our patented and unique polypeptide Bioquantine®) giving a boost to the effects on each one of our protocols, being the ED one of the most innovative of its kind in the world.

This in-office procedure may vary from patient to patient about the bio-material concentration and cell viability, but regularly it is performed under an aseptic technique using 1 mL of of BioActivated mesenchymal stem cells (biological scaffold that contains 125 million x ml) to apply in situ (nerves and/or intra-cavernous application) with an insulin needle [30-33].

For patients suffering an urological disorder or pathology the puncture site will be on the lateral face of the body of the penis, another application will be giving at cavernous body, for a total of 4 punctures. The puncture must be given near the root of the penis. During the application in some cases a tourniquet will be use on the root of the penis for the biomaterial concentration remain as long as possible on the corpora cavernosa. The duration shouldn't exceed 30 minutes.

The outcome will be noticeable from 8 days up to 24 days after the application and the bene9it may last from 6 up to 12 months. PENILE REJUVENATION with THE I-GUANA SHOT® stimulates new tissue growth and blood supply, resulting in improved, firmer and larger erections.


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A 15-minute procedure for lasting results penile rejuvenation therapy with THE I-GUANA SHOT® for men struggling with erectile dysfunction, achieve firmer, stronger and larger erections.

In this instance, growth factors communicate with the cells responsible for cell turnover, rejuvenating damaged and aged tissue.

The benefits of THE I-GUANA SHOT® may include Firmer and stronger erections, straightening of the penis, Increased sensation, enhances the effects of other therapies such as Sildenafil, low or nonallergic reaction.

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