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# Chronic, long-term administration of Vardenafil improves endothelial function and corrects hypogonadism in patients with type 2 diabetes mellitus. A longitudinal, prospective, randomized, placebo-controlled, double blind, clinical trial

Daniele Santi<sup>1,2</sup>, Alessandro Guidi<sup>2</sup>, Antonio Granata<sup>2</sup>, Elisa Pignatti<sup>3</sup>, Roberto Bozic<sup>5</sup>, Stefano Zaza<sup>6</sup>, Laura Roli<sup>4</sup>, Tommaso Trenti<sup>4</sup>, Cesare Carani<sup>1</sup> & Manuela Simoni<sup>1,2</sup>

## Author affiliations

**Background:** Endothelial dysfunction leads to cardiovascular complications in type 2 diabetes mellitus (T2DM), through a reduction of nitric oxide (NO)-mediated relaxation. Phosphodiesterase-5 inhibitors (PDE5i) have hemodynamic effects, improving NO levels.

**Aim:** To investigate if long term, chronic treatment with the PDE5i Vardenafil improves systemic endothelial function in men with T2DM.

**Methods:** A longitudinal, prospective, investigator-started, randomized, placebo-controlled, double-blind, clinical-trial was carried out. 54 male patients affected by T2DM diagnosed within the last 5 years were enrolled. 26 and 28 patients were assigned by permuted block randomization to the verum and placebo-group, respectively. The study consisted of an enrollment phase, a treatment phase (24 weeks)

(Vardenafil/placebo 10 mg twice-daily), and a follow-up phase (24 weeks). Parameters evaluated: International Index of Erectile Function (IIEF)-15, flow mediated dilation (FMD), intima media thickness (IMT), routine hematologic analyses. Serum testosterone (T) and its precursors were measured by liquid-chromatography tandem mass-spectrometry (LC-MS/MS). Gonadotropins were evaluated by ELISA.

Results: Only one serious adverse event was registered in the placebo group. The erectile function domain of IIEF-15 ( $P=0.049$ ) improved after treatment. At the end of the treatment phase FMD significantly increased ( $P=0.002$ ) while IMT ( $P=0.003$ ), fibrinogen ( $P=0.005$ ), white blood cells count ( $P=0.018$ ) and Red cells Distribution Width ( $P=0.028$ ) significantly decreased. FMD was significantly related to T serum levels ( $P=0.002$ ), which significantly improved after Vardenafil treatment only in hypogonadal men ( $T<10.4$  nmol/l) ( $P=0.023$ ), without changes in gonadotropin serum levels. Smoking-habits, hypertension and glycemic control influenced the hemodynamic and inflammatory parameters.

Conclusions: This is the first double-blind, placebo-controlled clinical-trial in which T2DM men are chronically treated with Vardenafil for 6 months, and followed-up for 6 months after therapy-withdrawal. Chronically administered Vardenafil is safe and effective in T2DM patients and improves both tissue oxygenation and inflammatory markers, but this effect is lost after therapy withdrawal. For the first time, we demonstrate that chronic Vardenafil therapy improves T (measured by LC-MS/MS) in diabetic, hypogonadal men, an effect possibly due to improved microcirculation in the testis (EudraCT number 2009-014137-25).

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## Authors

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