

Lifertil

Supplement of life



NF NElfarm

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Nelfarm LTD is based in Athens, Greece and has been dealing since 2018 with the development, production and distribution of parapharmaceutical supplements. Its portfolio includes high quality products that respond to specific customer needs.

Flagship of the company is Lifertil, a specialized food supplement with a composition that contributes to fertility and reproduction with very encouraging results. Around one in six couples experience difficulties in achieving conception at some stage during their reproductive years due to modern lifestyles, trends and difficulties. Lifertil was created to help treat this condition

Lifertil is a food supplement combining specialised ingredients to deal with infertility problems. It consists of two different recommendations, for women and men, focusing on treatment of the problems of each gender.

More specific,

Lifertil for women contains a special combination of ingredients that have a positive effect on female infertility conditions, such as disorders of the menstrual cycle and therefore ovulation, endometriosis, damage to the fallopian tubes (e.g. inflammation, blockage), polycystic ovary syndrome, abnormal secretion of hormones FSH and LH.

It contributes to:

- Normal fertility and reproduction
- Normal hematopoiesis and development of the maternal tissue during pregnancy
- Process of cell division
- Treatment of polycystic ovary syndrome (PCOS)
- Protection of cells from oxidative stress
- Normal functioning of the immune system
- Improvement of sexual desire and vaginal dryness

Lifertil for men consists of a specialized composition that affects the mechanisms of spermatogenesis, resulting in the treatment of the problems responsible for male infertility.

It contributes to:

- Normal fertility and reproduction
- Normal spermatogenesis
- Maintenance of normal testosterone levels in the blood
- Improvement of sperm parameters such as concentration, number, density, motility and morphology of sperm, DNA fragmentation and low viability of sperm
- Protection of cells from oxidative stress
- Normal functioning of the immune system



Συστατικά/Ingredients	Ανά ημερήσια δόση (2 δισκία)/ Per serving dose (2 tabs)	Δ.Τ.Α. / N.R.V. (%)*
Vitamin A (RE) (as Vitamin A acetate and 25% beta-Carotene)	2668 IU	105%
Vitamin D3 (as Cholecalciferol)	400 IU (10 µg)	200%
Vitamin E (a-TE) (as Vitamin E acetate)	18 mg (26,8 IU)	150%
Vitamin B1 (as Thiamine hydrochloride)	1,6 mg	145%
Vitamin B2 (Riboflavin)	2,1 mg	150%
Vitamin B3 (Niacin)	20 mg	125%
Vitamin B6 (as Pyridoxine hydrochloride)	3 mg	214%
Vitamin C (Ascorbic acid)	80 mg	100%
Vitamin B12 (Cyanocobalamin)	2 µg	80%
Pantothenic acid (as Calcium-D-pantothenate)	7,5 mg	125%
Folic acid	200 µg	100%
Biotin (D-Biotin)	62 µg	124%
Vitamin K1	30 µg	43%
Molybdenum (as Sodium molybdate)	50 µg	100%
Chromium (as Chromium picolinate)	40 µg	100%
Manganese (as Manganese sulfate)	2 mg	100%
Copper (as Copper (II) oxide)	0,5 mg	50%
Zinc (as Zinc picolinate)	30 mg	300%
Ferrous (as Ferrous fumarate)	4,2 mg	30%
Selenium (as Sodium selenite)	55 µg	100%
Iodine	150 µg	100%
Flaxseed oil microencapsulated (std.30% alpha-Linolenic acid, ALA-TG)	200 mg	*
Ashwaganda root extract (std.45% withanolides, <i>Withania somnifera</i> (L.) Dunal)	100 mg	*
<i>Mucuna pruriens</i> (L.) DC extract (std.15% L-DOPA)	100 mg	*
Alpha-Lipoic acid	100 mg	*
Acetyl -L- carnitine	100 mg	*
Milk thistle extract (std. 45% silymarin, <i>Silybum marianum</i> (L.) Gaertn.)	50 mg	*
Coenzyme Q10	10 mg	*
Astaxanthin microencapsulated (Std.2% from <i>H. pluvialis</i>)	1,6 mg	*



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Copper (as Copper (II) oxide)	0,5 mg	50%
Zinc (as Zinc picolinate)	10 mg	100%
Ferrous (as Ferrous fumarate)	4,2 mg	30%
Selenium (as Sodium selenite)	55 µg	100%
Iodine	150 µg	100%
DHA microencapsulated (std.10% DHA-TG)	200 mg	*
Myo-Inositol	200 mg	*
<i>Rhodiola rosea</i> root extract (std 3% rosavins)	100 mg	*
Alpha-Lipoic acid	100 mg	*
Damiana leaf extract (10:1) (<i>Turnera diffusa</i> Willd. ex Schult)	90 mg	*
Coenzyme Q10	10 mg	*
Green tea leaf extract (<i>Camellia sinensis</i> (L.) Kuntze) (std.50% polyphenols)	5 mg	*

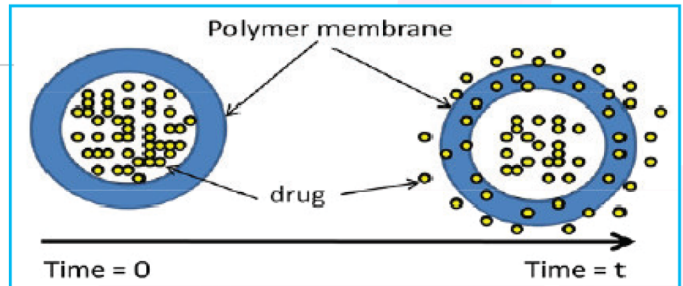
Controlled release

The product's ingredients are gradually released so that they cover the body all day and night.

The two following technologies have been used for this purpose:

01 Matrix system

Controlled diffusion systems, also known as matrix systems, are very popular for sustained release dosage forms. In this technology, the tablet has a casing typically made up of polymers. The type of polymer controls the release of the ingredients in the body. Various polymers are used to formulate controlled release dosage forms. Hydroxypropyl-methylcellulose (HPMC) is used as the first choice for forming hydrophilic matrix systems as it provides a powerful mechanism for controlled release of components.



02 Microencapsulated ingredients

This technique was used to solve the problem of low absorption and bioavailability of traditional low absorption active ingredient forms. The creation of components in microencapsulated particles surrounded by a coating improves the overtaking of the catastrophic components of the gastric system and helps the encapsulated component to be transferred to the cells and tissues. Lifertil contains the ingredients Astaxanthin, ALA, DHA in the form of microencapsulated ingredients.

Antioxidant action

Particular importance is given to the **antioxidant activity** of the product because oxidative stress is one of the main causes of infertility in men and women.

Herbal extracts

Selected herbal extracts for their proven effectiveness in improving fertility have been used in Lifertil.

The Action of Antioxidants

Antioxidants improve sperm quality, motility, pregnancy rate and oxidative stress (Figure 1). [1]

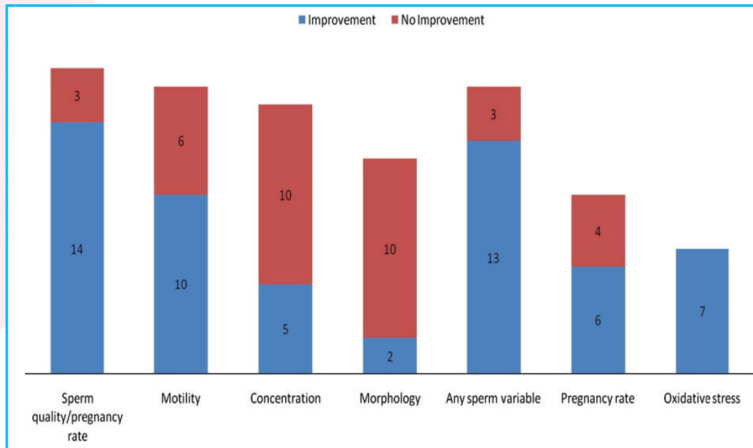


Figure 1. Effect of antioxidants on semen parameters, pregnancy rate and oxidative stress. Numbers indicate the number of studies that showed improvement or not. Antioxidants used in the study were: vitamin C, vitamin E, folic acid, zinc, selenium, carnitines, acetylcysteine, astaxanthin.

The antioxidant effect of astaxanthin

Astaxanthin has strong antioxidant and anti-inflammatory action. A pilot study using astaxanthin in a double-blind way reported a **significant reduction in free oxygen radicals in sperm and a decrease in serum inhibin B** (increased inhibin B inhibits follicle stimulating hormone and suppresses spermatogenesis) and this is associated with **improved motility and morphology of spermatozoa**. These parameters were associated with **higher monthly (23.1%) and overall (54.5%) pregnancy rates** than placebo (11.1% and 3.6%). [2]

Table 1. Sperm characteristics and hormone effects at baseline and after 3 months of treatment.

	Placebo (n=19)		Astaxanthin (n=11)	
	Preintervention	Postintervention	Preintervention	Postintervention
Testosterone (nmol/L)	15.6 ± 7.1	21.3 ± 6.1	16.7 ± 4.1	16.0 ± 2.1
Inhibin B (IU/L)	182 ± 89	152 ± 71	186 ± 123	133 ± 52
Sperm concentration (million/mL)	28.3 (16.3–49.2)	28.2 (17.1–46.3)	36.2 (25.1–56.1)	48.6 (29.0–81.4)
Linear velocity (µm/s)	25.3 ± 9.5	22.9 ± 9.8	22.1 ± 5.8	29.6 ± 8.1
Sperm morphology (% normal)	8.6 ± 5.2	10.0 ± 5.7	9.6 ± 7.1	11.4 ± 6.8
Reactive Oxygen Species (counts/s)	376 (96–1477)	490 (98–2450)	394 (74–2096)	99 (35.2–279.2)

References:

- Ross C, et al. A systematic review of the effect of oral antioxidants on male infertility. *Reprod Biomed Online*. 2010 Jun;20(6):711-23.
- Comhaire FH, El Garem Y, Mahmoud A, Eertmans F, Schoonjans F. Combined conventional/antioxidant "Astaxanthin" treatment for male infertility: a double blind, randomized trial. *Asian J Androl*. 2005 Sep;7(3):257-62.

Why α -linolenic acid?

Omega 3 fatty acids are essential for proper sperm function. The membrane of normal sperm contains long-chain omega-3 polyunsaturated fatty acids (PUFAs) at high concentration, namely docosahexaenoic acid (DHA), which ensures high fluidity in the membrane phospholipids. Sperm cell membranes in men with infertility contain less DHA and shows lower fluidity.

As a result of the decreased fluidity of the membrane, the ability of sperm cells to undergo an induced acrosome reaction and to merge with oocytes is reduced, which explains reduced fertility.

However, semen concentration and motility were inversely correlated with the dietary intake of long chain PUFAs EPA and DHA, but were positively correlated with the short-chain ω -3 PUFA α -linolenic acid (ALA).

This is because long-chain **DHA and EPA cannot pass through the blood-testicle barrier due to their high molecular weight, while the small chain of ALA can pass.** Thanks to the abundant presence of the necessary enzymes within the seminal tubules, ALA is metabolized in the long chain PUFA. [3]

The importance of L-acetylcarnitine

Carnitine administration in patients with weak semen improves many sperm parameters such as concentration, number, motility, and sperm morphology.

L-acetylcarnitine, in fact, has better results in increasing semen motility relative to L-carnitine (Figure 2). [4]

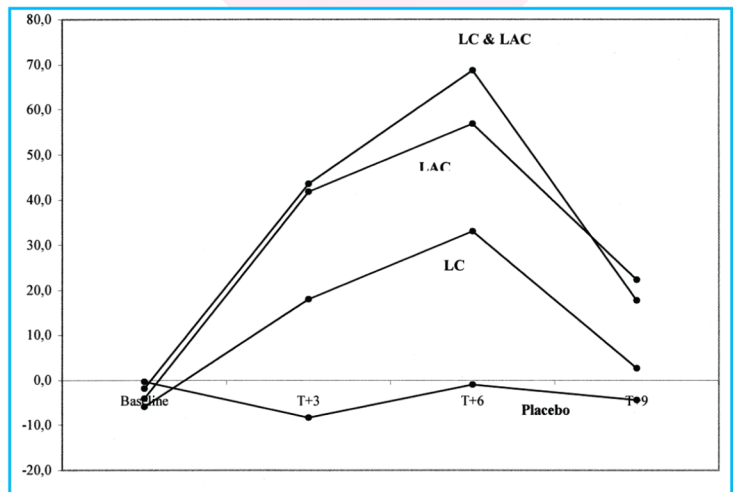


Figure 2. Increase of sperm motility after administration of L-carnitine (LC), of L-acetylcarnitine (LAC) or their combination (LC & LAC) in men with idiopathic asthenospermia.

3. Comhaire FH, Mahmoud A, An update on treatments and interventions for male infertility, and the role of nutraceutical food supplementation. *Journal of Pharmacy and Nutrition Sciences*, 2013, 3, 1-16.

4. Balercia G, Regoli F, Armeni T, Koverech A, Mantero F, Boscaro M. Placebo-controlled double-blind randomized trial on the use of L-carnitine, L-acetylcarnitine, or combined L-carnitine and L-acetylcarnitine in men with idiopathic asthenozoospermia. *Fertil Steril*. 2005 Sep;84(3):662-71.

Ashwagandha. Its action on sperm quality

A clinical study of the spermatogenic effect of Ashwagandha root extract (*Withania somnifera*) in men with oligospermia showed a **167% increase in sperm count**, a **53% increase in semen volume**, a **57% increase in sperm motility** and a **17% increase in testosterone levels in serum** (Figure 3) 90 days after starting treatment. [5]

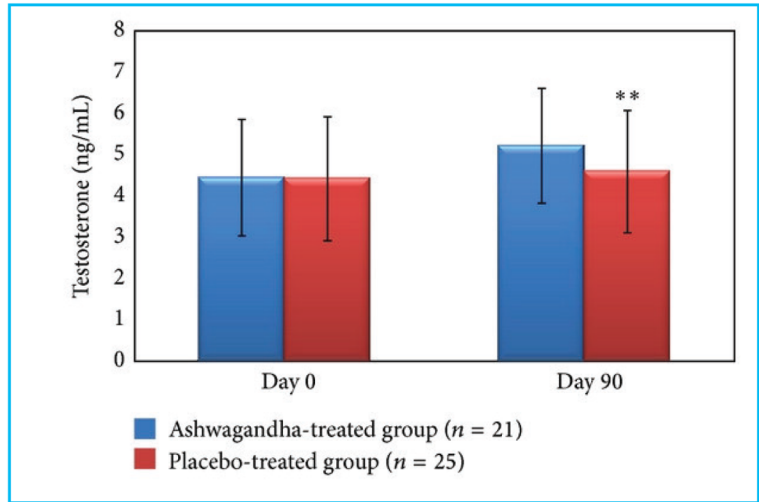


Figure 3. Serum testosterone levels (ng / ml) before and after administration of Ashwagandha root extract in patients with oligospermia.

Ashwagandha and stress reduction

Ashwagandha root extract is traditionally used in Ayurveda to reduce stress due to the plant's adaptive properties.

Clinical studies in men and women with chronic stress indicate that Ashwagandha reduces anxiety levels after 30 days of administration and even more after 60 days of administration (Figure 4). [6]

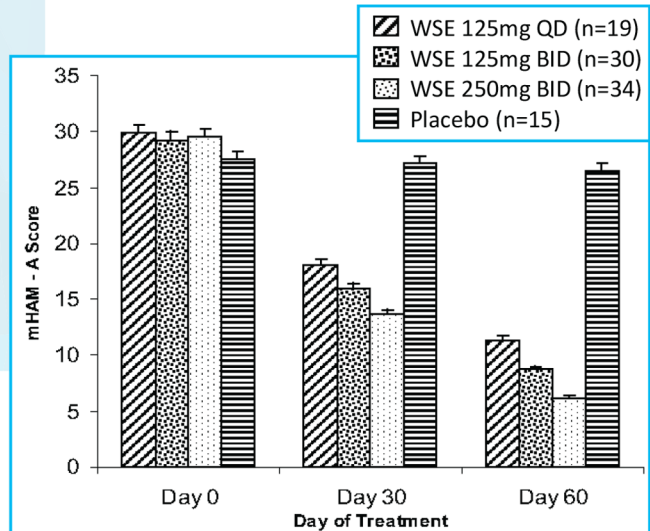
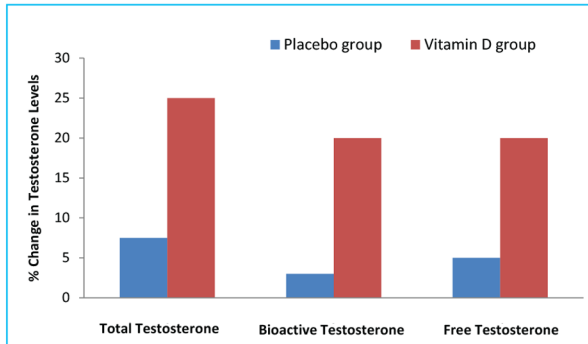


Figure 4. Average total cumulative stress and anxiety score based on a modified Hamilton anxiety scale per group on days 0, 30 and 60 of treatment with *Withania somnifera* extract or placebo.

5. Ambiyi VR, Langade D, Dongre S, Aptikar P, Kulkarni M, Dongre A. Clinical evaluation of the spermatogenic activity of the root extract of Ashwagandha (*Withania somnifera*) in oligospermic males: a pilot study. *Evid Based Complement Alternat Med*. 2013;2013:571420.

6. Biswajit A et al, A Standardized *Withania Somnifera* Extract Significantly Reduces Stress-Related Parameters in Chronically Stressed Humans: A Double-Blind, Randomized, Placebo-Controlled Study. *JANA* Vol. 11, No. 1, 2008.

Effect of Vitamin D on testosterone levels in men



Significant increases in total testosterone, bioactive testosterone and free testosterone levels were observed in a group of men who received vitamin D. On the other hand, there was no significant change in the placebo group (Figure 5). [7]

Figure 5. Testosterone levels of healthy men who participated in a randomized controlled study receiving either 83µg (3.332 IU) of vitamin D daily or placebo for 1 year.

Mucuna pruriens, the adaptogenic plant with effect in fertility

Mucuna pruriens is a plant that is one of the most important superfoods, as its activity extends to many areas, giving enormous benefits to the human body. It has tonic, strengthening, aphrodisiac and other properties.

Clinical studies in infertile men showed that sperm count and motility were significantly recovered after administration of *Mucuna pruriens* for 3 months (Table 2). [8]

Table 2. Clinical parameters of patients before and after treatment with *Mucuna pruriens*.

Clinical parameters of patients before and after treatment with <i>M. pruriens</i>							
Physiologic parameters	Control	Normozoospermic		Oligozoospermic		Asthenozoospermic	
		Pretreatment	Posttreatment	Pretreatment	Posttreatment	Pretreatment	Posttreatment
Semen volume (mL)	2.70 ± 0.32	2.56 ± 0.47 (-5)	2.78 ± 0.61 (+8)	2.65 ± 0.35 (-2)	2.72 ± 0.43 (+3)	2.18 ± 0.40 (-19)	2.29 ± 0.19 (+5)
Liquefaction time (min)	20.85 ± 2.22	25.10 ± 2.92 ^a (+20)	19.40 ± 2.16 ^b (-23)	24.15 ± 1.79 (+16)	18.75 ± 2.49 ^b (-22)	58.10 ± 6.38 ^c (+179)	35.80 ± 4.96 ^b (-38)
Motility (%)	56.75 ± 5.05	62.50 ± 6.44 ^d (+10)	67.15 ± 6.27 (+7)	68.00 ± 9.60 (+20)	70.80 ± 15.45 (+4)	12.85 ± 2.39 ^c (-77)	18.10 ± 2.86 ^b (+41)
Sperm concentration (x10 ⁶ /mL)	58.07 ± 7.61	56.10 ± 7.31 ^d (-3)	70.65 ± 7.17 ^b (+26)	8.31 ± 2.82 ^c (-86)	56.20 ± 6.69 ^b (+576)	54.55 ± 6.37 (-6)	57.70 ± 9.16 (+6)

Note: Results are expressed as mean ± SD. Values in parenthesis indicate percentage change (pretreatment groups vs. control and posttreatment groups vs. respective pretreatment groups).

^aP<.05 vs. control group, ^bP<.001 vs. pretreatment group, ^cP<.001 vs. control group, ^dP<.01; vs. control group.

7. Pilz S et al, Effect of vitamin D supplementation on testosterone levels in men. *Horm Metab Res.* 2011 Mar;43(3):223-5.

8. Shukla KK et al, *Mucuna pruriens* improves male fertility by its action on the hypothalamus-pituitary-gonadal axis. *Fertil Steril.* 2009 Dec;92(6):1934-40.

Milk thistle, detoxification and hepatoprotection

Milk thistle has been used since antiquity to treat a series of liver and gallbladder disorders, including hepatitis, cirrhosis and jaundice.

Today, thistle milk is primarily recognized as a healing and hepato-protective agent, especially in cases of cirrhosis, chronic hepatitis, alcohol consumption, and exposure to environmental toxins. [9]

The elimination of toxins from the liver and the regulation of metabolism positively affect male fertility.

There is evidence that thistle milk can be hepato-protective through a number of mechanisms: antioxidant action, membrane-level toxin exclusion, increased protein synthesis, anti-inflammatory activity and possible immunomodulatory effects. [9]

Zinc improves all semen parameters

Numerous scientific studies have shown the impressive results of zinc in sperm parameters.

In particular, it **improves the vitality, morphology and motility of the spermatozoa (Table 3).** [10]

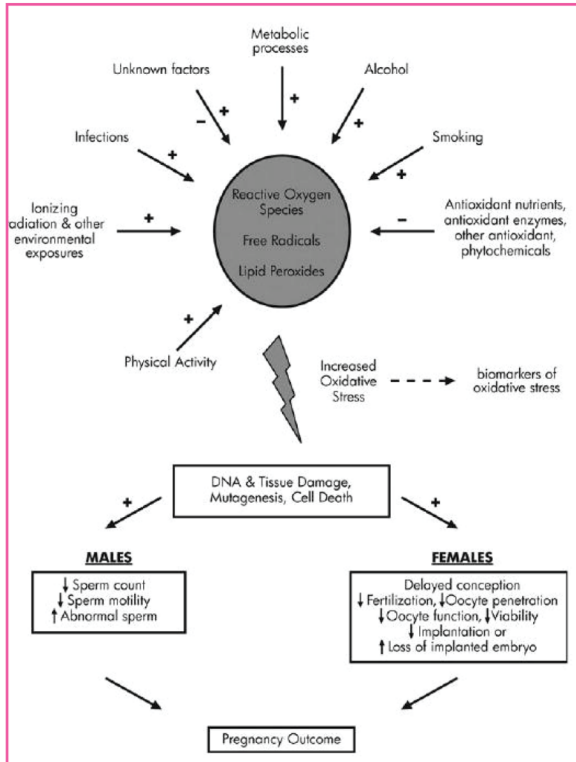
Parameter	Initial	After 4 months
Seminal plasma zinc (mg%)	7.89 ± 2.95	21.18 ± 13.68*
Serum zinc (mcg%)	87.78 ± 21.08	108.33 ± 39.20
Progressive motility (%)	21.36 ± 21.41	34.64 ± 27.90*
Viability (% live)	60.33 ± 17.28	70.77 ± 15.25
Morphology (% normal)	56.75 ± 10.82	72.69 ± 11.48**
*P<0.05 **P<0.01		

Table 3. Effect of oral zinc sulphate administration on zinc levels in serum and sperm and semen parameters

9. Mulrow C et al, Milk thistle: effects on liver disease and cirrhosis and clinical adverse effects. *Evid Rep Technol Assess (Summ)*. 2000;(21):1-3.

10. Tikkiwal M, Ajmera RL, Mathur NK, Effect of zinc administration on seminal zinc and fertility of oligospermic males. *Indian J Physiol Pharmacol*. 1987 Jan-Mar;31(1):30-4.

The role of antioxidants in female infertility



Oxidative stress induces lipid peroxidation, structurally and functionally alters proteins and DNA, promotes apoptosis and contributes to the risk of chronic conditions such as cancer and heart disease.

In vitro data, animal model and clinical studies indicate that oxidative stress plays a role in the etiology of adverse reproductive events in both women and men (Figure 6). [11]

Figure 6. Role of oxidative stress in fertility

Folic acid before conception TOO

Folic acid is necessary during pregnancy to protect and meet the increased needs of the pregnant woman and the fetus.

Folic acid, taken orally prior to conception and during the first stages of pregnancy, plays a role in the **prevention of neural tube defects** and has been associated with the prevention of other congenital folic acid-related abnormalities such as **cardiac abnormalities, abnormalities of the urinary tract, defects of the limbs.** [12]

Beneficial
action even
before
conception

11. Ruder EH, Hartman TJ, Blumberg J, Goldman MB, Oxidative stress and antioxidants: exposure and impact on female fertility. *Hum Reprod Update.* 2008 Jul-Aug;14(4):345-57.

12. Wilson RD et al, Pre-conception folic acid and multivitamin supplementation for the primary and secondary prevention of neural tube defects and other folic acid-sensitive congenital anomalies. *J Obstet Gynaecol Can.* 2015 Jun;37(6):534-52.

Omega 3 fatty acids (DHA)

The effect of omega 3 fatty acids, as a nutritional supplement, on health is widely recognized. Adequate intake of omega 3 fatty acids, and in particular EPA and DHA, may increase the duration of pregnancy and improve the cognitive and visual performance of infants. Sufficient levels of omega 3 fatty acids have also been shown to reduce the incidence of premature birth in some populations.

Pregnant women, as well as those wishing to conceive, often consume low levels of omega 3 fatty acids because they are mainly found in fish that many avoid because of concerns about possible heavy metal contamination. It is important in prenatal care that women's diets ensure daily intake of 200 to 300 mg of omega 3 fatty acids from dietary supplements. [13]

Rhodiola rosea to adjust the menstrual cycle

In a study of 40 women suffering from amenorrhea (loss of menstrual cycles), 100 mg *Rhodiola rosea* was administered twice a day for 2 weeks. In some women, the pattern was repeated 2-4 times. Normal menstruation was restored in 25 women, 11 of whom became pregnant (Figure 7). [14]

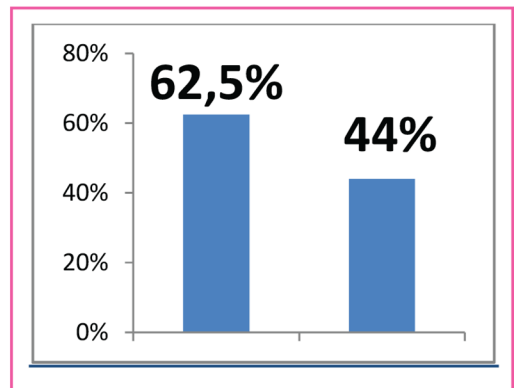


Figure 7. 62,5% restoration of normal menstruation and 44% pregnancy achievement by treatment with *Rhodiola rosea*.

13. Jordan RC, Prenatal omega-3 fatty acids: review and recommendations. *J Midwifery Womens Health*. 2010 Nov-Dec;55(6):520-8.

14. Khanum F, Bawa AS, Singh B, *Rhodiola rosea: a versatile adaptogen*. Vol. 4, 2005—*Comprehensive reviews in food science and food safety*.

Myoinositol in the treatment of Polycystic Ovarian Syndrome

Myoinositol is one of the most interesting molecules studied for the treatment of Polycystic Ovarian Syndrome (PCOS).

In a clinical study of 3602 patients with PCOS and infertility, myoinositol and folic acid were co-administered for 3 months. According to the results, 70% (2520 women) improved their menstrual cycle. Among them, a total of 15.1% became pregnant (545 women).

In a subgroup of 32 patients who were evaluated for hormonal values before and after treatment, a significant improvement in androgen levels and an increase in progesterone values were observed (Figure 8). [15]

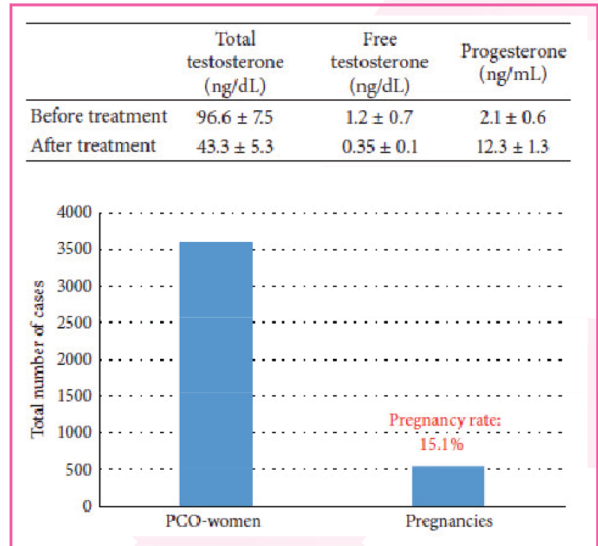


Figure 8. Hormone levels before and after administration of myoinositol. Number of patients and rate of pregnancy after treatment.



15. Regidor PE, Schindler AE, Myoinositol as a Safe and Alternative Approach in the Treatment of Infertile PCOS Women: A German Observational Study. *Int J Endocrinology* Vol 2016, 5 pages.

Vitamin E for normal endometrial thickness

Scientific studies show that among the factors responsible for thin endometrium is the high blood flow resistance of the uterine artery arteries.

Vitamin E has been shown to improve capillary blood flow in a variety of organs not only by inhibiting lipid breakdown in red blood cell membranes but also by protecting the endothelium from oxidative stress.

In an attempt to improve the endometrium thickness, vitamin E was administered in patients with thin endometrium in order to improve the Radial Artery - Resistance Index (**RA-RI**) of the uterus in blood flow and increase of endometrial thickness.[16]

01

Vitamin E improved RA-RI in 18 (72%) of 25 patients and the endometrial thickness in 13 (52%) of 25 patients (Table 4).

02

The effect of vitamin E was also examined histologically in the endometrium (n = 5). Vitamin E improved glandular epithelial growth, blood vessel growth and expression of vascular endothelial growth factor proteins in the endometrium.

Table 4. Effect of vitamin E on RA-RI, endometrial thickness and pregnancy rate.

Effects of Vitamin E on RA resistance index and endometrial thickness in the patients with a thin endometrium								
	n	RA-RI			EM (mm)			
		Previous cycle	Treatment cycle	No. of <0.81 (%)	Previous cycle	Treatment cycle	No. of <0.81 (%)	No. of pregnancies (%)
Control	10	0.866 (0.814-0.908)	0.866 (0.729-0.895)	1 (10)	7.3 (6.0-7.8)	6.8 (6.0-10.0)	1 (10)	0 (0)
Vitamin E	25	0.861 (0.812-0.948)	0.780 (0.690-0.895)	18 (72)	7.2 (5.5-7.8)	8.3 (5.2-11.0)	13 (52)	5 (20)

16. Takasaki A et al, Endometrial growth and uterine blood flow, a pilot study for improving endometrial thickness in the patients with a thin endometrium. *Fertility and Sterility* Vol. 93, No. 6, April 2010.

Damiana (*Turnera diffusa*), powerful antioxidant and aphrodisiac

Damiana (*Turnera diffusa*) is a plant from South and Central America. Its leaves have a strong antioxidant effect.

The ability of *Turnera* extract to inhibit oxidation is proportional to its concentration and comparable to the antioxidant action of vitamin E (α-tocopherol) (Figure 9). [17]

Damiana is also traditionally used as a tonic for the central nervous and hormonal system and as an aphrodisiac in Latin America.

Supplying a dietary supplement containing Damiana to women for one month showed improvement in sexual desire, decreased vaginal dryness, increased sexual intercourse and orgasm and improved clitoral sensation. [18-19]

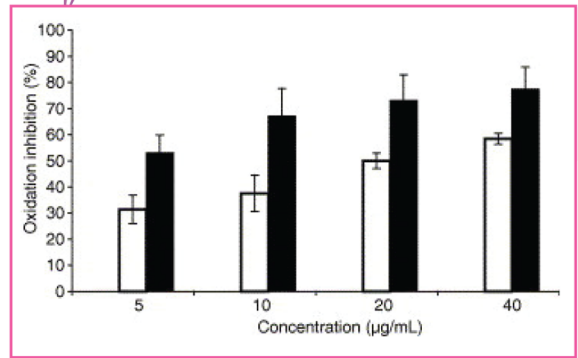


Figure 9. Inhibition of oxidation by hydroethanolic extract of *T. ulmifolia* L. 50% at different concentrations. A-tocopherol was used as a reference antioxidant.

□ *T. ulmifolia* L. ■ α-tocopherol

Green tea to reduce oxidative stress

Reactive Oxygen Species (ROS) exist in low concentrations in the genitals of male and female individuals. Their excessive growth leads to oxidative stress that damages DNA, lipids and proteins. In females, oxidative stress involved in the maturation of oocytes and can inhibit in-vitro maturation of the oocyte.

The excellent antioxidant action of green tea catechins is the key in improving fertility through the reduction of oxidative stress.

In particular, French epigallocatechin-3 (EGCG) is considered to be the most promising bioactive compound in green tea due to its strong antioxidant activity. [20]

17. Nascimento MA et al, *Turnera ulmifolia* L. (Turneraceae): preliminary study of its antioxidant activity. *Bioresour Technol.* 2006 Aug;97(12):1387-91.

18. Suresh Kumar, Ruchi Taneja, and Anupam Sharma, *The Genus Turnera: A Review Update.* *Pharm Biol* 2005, Vol. 43, No. 5, pp. 383–391.

19. Ito TY, Trant AS, Polan ML, *A double-blind placebo-controlled study of ArginMax, a nutritional supplement for enhancement of female sexual function.* *J Sex Marital Ther.* 2001 Oct-Dec;27(5):541-9.

20. Roychoudhury S, Agarwal A, Virk G, Cho CL, *Potential role of green tea catechins in the management of oxidative stress-associated infertility.* *Reprod Biomed Online.* 2017 May;34(5):487-498.



Lifertil  **Supplement of life**



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