

SALWA A. ELGEBALY, M.Sc., Ph.D.

Curriculum Vitae

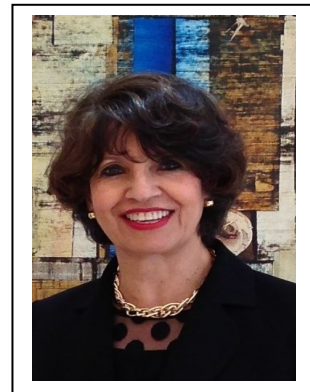
Current Position:

2006 - Present

Founder & CEO

Nour Heart, Inc.
Virginia, USA
Cell: 860-680-8860 (Text Only)
E-mail: selgebaly@nourheart.com

Nour Heart, Inc. is a U.S. Research and Development (R&D) Biomedical company established in Hartford, CT.



2019 – Present

Professor, University of Connecticut Faculty of Medicine (Adj.) Farmington, Connecticut, U.S.

Professional Expertise:

Overall Summary:

- Dr. Elgebaly is the founder and CEO of the R&D Biotech Company, Nour Heart, Inc. The aim of the Company is to develop Cyclocreatine Phosphate as a new cardioprotective drug for patients with ischemic heart disease.
- ***Nour Heart is, also, developing the cardiac-derived inflammatory mediator, Nourin® as a novel biomarker for the early diagnosis of Angina patients with chest pain seen in hospital emergency department (ED) and in outpatient clinics.***
- ***She is the Inventor of nine (9) Patents Issued by the U.S. Patent Office and two pending applications.***
- ***Nour Heart has been recently granted the FDA Orphan Drug Designation for the Company's new drug Cyclocreatine Phosphate with the unique FDA designation for: prevention of ischemic injury to enhance cardiac graft recovery and survival in heart transplantation (DRU-2015-4951).***
- Recently, Dr. Elgebaly has submitted a Pre-IND application to the FDA for their review and recommendations on the Company's proposed Phase I clinical trial.
- Dr. Elgebaly's unique experience in academic drug discovery and development, she has extensive experience in clinical trials (FDA-regulated Phase II and Phase III trials), pharmaceutical industry (Director of Clinical Affairs), as well as FDA filing for drug registration for human use.
- Dr. Elgebaly previously held the position of Director of Clinical Affairs in the pharmaceutical company, AnGes Inc. in Maryland, and she established in Connecticut and functioned as the Director of the two new Clinical Trials and Research Centers at the Investigative Sites; Grove Hill Medical Center and Connecticut Multispecialty Group.

- Because of Dr. Elgebaly's *Nourin*® technology as a novel early biomarker for ACS patients, she is an active participant with the *FDA-sponsored Cardiac Safety Research Consortium-CSRC*.
- **Review Article:** **Elgebaly SA**, Poston R, Todd R, Helmy T, Almaghraby A, Elbayoumi T, Kreutzer DL.: Cyclocreatine Protects Against Ischemic Injury and Enhances Cardiac Recovery During Early Reperfusion. *Expert Review of Cardiovascular Therapy*, Volume 17(9), 683-697, 2019.

Academic:

- Research & Development for heart-related diagnostic and therapeutic products.
- Clinical trials in pharmaceutical setup and investigative sites (patients).
- FDA requirements for product submission for approval.
- Participant, FDA-Sponsored Cardiac Safety Research Consortium.
- Dr. Elgebaly's research resulted in the discovery of the potent tissue-derived inflammatory mediator, *Nourin* and its antagonists *Cyclosporin H* (anti-inflammatory) and the cardioprotective *Cyclocreatine* (anti-inflammatory & anti-apoptotic).
- Dr. Elgebaly has been awarded millions of dollars to support her research from such organizations as the NIH, academic institution such the University of Connecticut Faculty of Medicine as well as the Maryland Technology Development Cooperation, several pharmaceutical companies, corporate competitive awards and private funding.
- Dr. Elgebaly has over 79 publications and one review article, as well as 9 Issued Patents by the U.S. Patent Office and one pending patent application. She published in peer-reviewed journals, including: *Science*, *J. Thoracic & Cardiovascular Surgery*, *J. Molecular and Cellular Cardiology*, *J. Pathology*, *J. Transplantation*, *J Expert Review of Cardiovascular Therapy*, *J. Urology*, *J Pharmacology Experimental Therapy*, *American Journal of National Cancer Institute*, *Current Eye Research*, and *Journal of Ophthalmology and Visual Science*.
- Dr. Elgebaly is also a frequent lecturer in international conferences on the subject of *Nourin*, *Cyclosporin H*, and *Cyclocreatine Phosphate*. Specifically, Dr. Elgebaly was invited to present her work by:
 1. *Nobel Prize Winner in Medicine, Professor Sir John Vane, London, UK,*
 2. *Nobel Prize Winner in Medicine, Professor R. Levi Montalcini, Rome, Italy,*
 3. *Professor Sir Magdy Yacoub in London, United Kingdom.*

Product Commercialization:

A) Cyclocreatine Phosphate and FDA Orphan Drug Designation

Nour Heart was granted the Orphan Drug Designation (ODD) by U.S. Food and Drug Administration for its new patented drug Cyclocreatine Phosphate for the unique designation of: ***prevention of ischemic injury to enhance cardiac graft recovery and survival in heart transplantation*** (DRU-2015-4951) (also see ***attachment A below***).

B) Cardiac Nourin Blood Test

Nourin is a potent inflammatory mediator rapidly released within minutes by ischemic and necrotic myocardium. *Nourin* can diagnose ACS patients (UA and AMI) presenting to Emergency Departments ED with chest pain. Currently, Nour Heart is developing the *Nourin* test as a quickly ***rule in or out*** AMI patients and UA presenting with chest pain in hospital ED.

Clinical Research and Clinical Trial Expertise:

Dr. Elgebaly has extensive experience in clinical trials as FDA-regulated drug tested Phase II and Phase III trials (also see **attachment B below**), pharmaceutical industry (Director of Clinical Affairs), as well as FDA filing for drug registration for human use. Dr. Elgebaly previously held the position of Director of Clinical Affairs in the pharmaceutical company, AnGes Inc. in Maryland, and she established in Connecticut and functioned as the Director of the two new Clinical Trials and Research Centers at the Investigative Sites; Grove Hill Medical Center and Connecticut Multispecialty Group. She successfully managed over 26 clinical studies and worked closely with over 80 physicians and surgeons. Furthermore, because of Dr. Elgebaly's *Nourin* technology as a novel early biomarker for ACS patients, she is an active participant with the *FDA-sponsored Cardiac Safety Research Consortium-CSRC*. Currently, Dr. Elgebaly functions as a volunteer Official Consultant/Expert for the Egyptian Parliament for their efforts to establish the new Clinical Trials Law and the new *Law to Govern Animal Facilities and Animal Use in Research*.

Education:

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| 1979 | Ph.D. in Medicinal Chemistry (Oncology)
University of North Carolina, Chapel Hill
School of Pharmacy
Department of Medicinal Chemistry
Chapel Hill, North Carolina |
| 1975 | MS in Oncology
University of Wisconsin, Madison
School of Medicine, Oncology Department
Madison, Wisconsin |
| 1973 | B.Sc. in Pharmacy with Honors
University of Alexandria, Alexandria
School of Pharmacy, Alexandria, Egypt. |

Postgraduate Training:

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| 1979-1981 | Postdoctoral Fellow
Department of Pathology
University of Connecticut School of Medicine
Farmington, CT 06030 |
| 1998 | Completed an extensive course on "Drug Development & FDA Regulations" – Society of Clinical Research Associates. |
| 2006 | Completed an extensive course on "Study Monitoring & Auditing According to FDA and International Guidelines" with the Society of Clinical Research Associates (SOCRA). |

Appointments:

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| 2006 - Present | President & CEO
Nour Heart, Inc.
Nour Heart is a Biomedical Company that holds the U.S. issued patents and pending patent applications for the tissue-derived inflammatory mediator Nourin and its |
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antagonists *Cyclosporin H* (anti-inflammatory) and *Cyclocreatine Phosphate* (anti-apoptotic). Nour Heart is developing diagnostic and therapeutic products for patients with ischemic heart disease. Nour Heart is a member of the FDA-sponsored Cardiac Safety Research Consortium.

- 2007 – 2012** **Adjunct Assistant Professor**
United States Naval Academy
Annapolis, Maryland
- 2003-2006:** **Director, Nourin Preclinical and Clinical Development Program**
Inverness Medical Innovations
Boston, MA
- 2002 – 2003** **Director, Clinical Affairs**
AnGes, Inc.
9210 Corporate Boulevard, Suite 130
Rockville, MD 20850
- 2000 – 2002** **Director, Clinical Trials & Research**
Connecticut Multispecialty Group
Hartford, CT
- 1998-2000** **Director, Clinical Trials & Research**
Grove Hill Medical Center
300 Kensington Ave, New Britain, CT
- 1992-1995** **Associate Professor**
Department of Surgery, University of Connecticut School of Medicine and
Hartford Hospital and Farmington, CT 06030
- 1987-1988** **Director, Surgical Research Center**
Department of Surgery, University of Connecticut School of Medicine
Farmington, CT 06030
- 1986-1991** **Assistant Professor**
Department of Surgery, University of Connecticut School of Medicine,
Farmington, CT 06030
- 1981-1985** **Instructor**
Department of Surgery, University of Connecticut School of Medicine,
Farmington, CT 06030

Teaching Activities:

- 1986 – 1992** **Assistant and Associate Professor**
Department of Surgery
University of Connecticut School of Medicine, Farmington, CT
- Medical Students and Post-Doctoral Fellows
Topic: inflammation and tissue injury

Management:

Dr. Elgebaly managed her own laboratory as a Principal Investigator at the University of Connecticut School of Medicine. During that period, Dr. Elgebaly, supervised over 40 employees, including surgical residents, cardiology fellows, postdoctoral fellows, medical and graduate students, college and high school students, and a number of technicians.

Dr. Elgebaly responsibilities involved supervising the overall directions of various projects, writing grants and scientific articles, presenting scientific results in various conferences, and managing various funds. As a Director of Clinical Trials & Research at Grove Hill Medical Center and Connecticut Multispecialty, Dr. Elgebaly established the two Clinical Trials & Research departments and successfully managed over 26 clinical studies and worked closely with over 80 physicians and surgeons.

Honors and Awards:

1973	B.Sc. in Pharmacy with Honors
1973-1975	Predoctoral Fellowship, Madison, Wisconsin
1976-1979	Predoctoral Fellowship, Chapel Hill, NC
1979-1980	Postdoctoral Fellowship, Farmington, CT
1985	Selected for inclusion in <i>World Who's Who of Women</i>
1998	Selected for inclusion in <i>Who's Who in American Inventors</i>
2007-2010	Awarded by <i>Women in Bio</i> , Maryland.
2019-Present	Marquis <i>Who's Who</i>

Community Service:

2006 – Present	Scientific Reviewer - Bibliotheca Alexandrina Research Grants and Special Projects Alexandria, Egypt
2005 - Present	Established a new Clinical Trials Center at the University of Alexandria Faculty of Medicine, Alexandria, Egypt. Currently, I am a volunteer consultant.
2002 – Present	Invited Speaker on how to conduct clinical trials According to FDA & International Guidelines & Regulations.
2012 – 2016	Governor's Commission on Middle Eastern American Affairs, Maryland Conference Chair, <i>Middle Eastern American Women: Realities & Perceptions</i> May 5, 2013 - www.middleeastern.maryland.gov
2000 – 2018	Association of Egyptian American Scholars http://www.aeascholars.org/AEAS-Directory-Full.pdf
2010 - 2012	Commissioner for Women, Anne Arundel County, Maryland Conference Chair, <i>Unveiling the Mystique about the American Muslim Women</i> October 22, 2011
2004 - 2007	Vice Chair and Member of the Baltimore-Luxor-Alexandria Sister City Committee (BLASCC), Baltimore, Maryland.

- 2000 - 2002** Founding President, ANSAR's For Kids (non-profit organization for Bosnian Children) Hartford, Connecticut.
Nominated for the "Walter Cronkite Faith and Freedom Award" By Congressman Rob Simmons of Connecticut.
- 2000 - 2001** Co-Chair, Hartford Prayer Breakfast.

Patents Issued from the U.S. Patent Office, Washington DC:

1. ***Elgebaly SA***: Diagnostic Marker (#7,659,091)
2. ***Elgebaly SA*** and Elliott Schiffmann: Mitochondrial Marker of Ischemia – (#7,662,571)
3. ***Elgebaly SA & Elliott Schiffmann***: Methods to Prevent & Treat Diseases (# 8,288,350)
4. ***Farghaly A & Elgebaly SA***: Phosphagen Synthesis (# 7,964,736)
5. ***Elgebaly SA, Elliott Schiffmann & Tamer Elbayoumi***: Norexin-4 Nano-Lipid Emulsions (#8,333,987)
6. ***Elgebaly SA***: Methods for Restoring Functionality in Muscle Tissue (#5,091,404)
7. ***Elgebaly SA***: Biological Mediators of Immune Function (#5,403,914)
8. ***Elgebaly SA***: Antibodies to a Neutrophil Chemotactic Protein (#5,606,027)
9. ***Elgebaly SA***: Diagnostic Test Procedure for Urinary Tract Inflammatory Condition (#5,318,891).

Selected Publications:

Dr. Elgebaly's **publications** appeared in prestigious journals such as:

- Science
- Oncology
- Journal of Pathology
- American Journal of National Cancer Institute
- Journal of Urology
- Journal of Thoracic & Cardiovascular Surgery
- Journal of Molecular and Cellular Cardiology
- Investigative Journal of Ophthalmology and Visual Science
- Journal of Transplantation
- J Pharmacology Experimental Therapy
- J Expert Review of Cardiovascular Therapy
- Current Eye Research
- Surgical Forum.

Dr. Elgebaly **presented** her work at the following prestigious scientific conferences:

- American Heart Association
- American College of Surgeons
- American Association of Immunologists
- Society for Cardiovascular Angiography and Interventions
- The Association for Research in Vision and Ophthalmology
- International Society for Heart Research (ISHR)
- World Congress of the International College of Surgeons.

Selected Publications and Some Abstracts are listed below:

1. Lee KH, Hall IH, Mar EC, Starnes CO, **Elgebaly SA**, Waddel TG, Hadgraft RI, Ruffner EG and Weidner I: Sesquiterpene anti-tumor agents: inhibitors of cellular metabolism. **Science** 196:533-536, 1977.
2. **Elgebaly SA**, Hall IH, Lee KH, Sumida Y, Imakura Y and Wu RY: Antitumor agent XXVI: effect of brutasol, bruceoside A and bruceantin on P-388 lymphocytic leukemia cell respiration. **J Pharm Sci** 68(7):888-890, 1979.
3. Varani J, Lovett EJ III, **Elgebaly SA** and Lundy J: *In vitro* and *in vivo* adherence of tumor variants correlated with malignant potential. **Am J Pathol** 111:345-353, 1980.
4. **Elgebaly SA**, Varani J, Kunkel SL and Ward PA: Cyclic AMP levels in subpopulations of tumor cells: correlation with *in vitro* and *in vivo* behavior. **Oncology** 39:163-166, 1982.
5. **Elgebaly SA**, Forouhar F and Dore-Duffy P: Thiabendazole-induced suppression of renal damage in a murine model of autoimmune disease. **Am J Pathol** 115:204-211, 1984.
6. **Elgebaly SA**, Forouhar F, Gillies C, O'Rourke J and Kreutzer DL: Leukocyte-mediated injury to corneal endothelial cells: a model of tissue injury. **Am J Pathol** 116(3):407-416, 1984.
7. **Elgebaly SA**, Gillies C, Forouhar F, Hashem M, Baddour M, O'Rourke J and Kreutzer DL: An *in vitro* model of leukocyte-mediated injury to the corneal epithelium. **Curr Eye Res** 4(1):31-41, 1985.
8. **Elgebaly SA**, Barton R and Forouhar F: Reversal of radiation-induced leukemogenesis in mice by immunomodulation with thiabendazole and dinitrofluorobenzene. **J Natl Cancer Inst** 74(4):811-815, 1985.
9. **Elgebaly SA**, Herkert N, Gillies CC, Picciano PT, Donaldson MC, Kreutzer DL. Influence of anti-endothelial cell antibodies on the interactions of leukocytes with vascular endothelial cells in vitro. **J Exp Pathol**. 1985 Spring;2(1):59-73. PubMed PMID: 3915999.
10. **Elgebaly SA**, Herkert N, O'Rourke J and Kreutzer DL: Characterization of neutrophil and monocyte-specific chemotactic factors derived from isolated corneas in response to immunologic injury. **Am J Pathol** 126:22-32, 1987.
11. **Elgebaly SA**, Downes R, O'Rourke J and Kreutzer DL: Characterization of inflammatory mediators such as leukocyte chemotactic factors produced by isolated corneas in response to alkali injury. **Curr Eye Res** 6:1263-1274, 1987.
12. **Elgebaly SA**, Kozol RA, Masetti P, Bohr M and Lennan C: Release of neutrophil chemotactic factors from ischemic myocardial tissues. **Surg Forum** 38:276-279, 1987.
13. **Elgebaly SA**, Masetti P, Forouhar F, Rossomando EF, Cohen A. Ibuprofen fails to inhibit the release of the tissue-derived neutrophil chemotactic factors "Nourin" from ischemic hearts. XXVI World congress of the International College of Surgeons. July 3-9, Milan, Italy, 1988.
14. **Elgebaly SA**, Masetti P, Allam M and Forouhar F: Cardiac-derived neutrophil chemotactic factors: preliminary biochemical characterization. **J Mol Cell Cardiol** 21:585-593, 1989.

15. Kozol RA, Downes RA, Kreutzer DL, Wentzel S, Rossomando FF and **Elgebaly SA**: Release of neutrophil chemotactic factors from gastric tissue: initial biochemical characterization. **Dig Dis Sci** 34:681-687, 1989.
16. **Elgebaly SA**, Kozol RA and Kreutzer DL: Alcohol and immune system: role of gastric tissue. In: Alcohol Immunomodulation and AIDS Proceedings (Pawlowski A, Seminara D, Watson R, eds). AR Liss, Inc.: New York, Vol. 325, pp 75-78, 1989.
17. Kozol RA and **Elgebaly SA**: Ethanol and its effect on mucosal immunity. In: Drugs of Abuse and Immune Function (Watson R, ed). CRC Press: Colorado, pp 165-173, 1989.
18. Kozol RA, Punzo A, Ribaud R, Rossomando EF and **Elgebaly SA**: Neutrophil chemotactic activity in gastric secretions. **Arch Surg** 125(4):454-456, 1990.
19. Ruby ST, Allam M, Gallo M, Barth S and **Elgebaly SA**: Release of chemotactic factors by veins during preparation for arterial bypass. **Arch Surg** 125(4):481-485, 1990.
20. **Elgebaly SA**, Donshik P, Rahhal F and Williams W: The detection of neutrophil chemotactic factors in tears of giant papillary conjunctivitis patients: role of conjunctival tissue. **Invest Ophthalmol Vis Sci** 32:208-213, 1991.
21. Ehlers W, Williams W and **Elgebaly SA**: Conjunctiva-derived neutrophil chemotactic factors: preliminary biochemical characterization. **CLAO J** 17:65-68, 1991.
22. Riley M and **Elgebaly SA**: Release of a neutrophil chemotactic factor from UV-irradiated rabbit corneas. **Curr Eye Res** 9(7):677-682, 1990.
23. **Elgebaly SA**, Allam ME, Rossomando EF, Forouhar F, Farghaly A and Kreutzer DL: Cyclocreatine inhibits the production of neutrophil chemotactic factors from isolated hearts. **Am J Pathol** 137:1233-1241, 1990.
24. **Elgebaly SA**, Miano D, Fishman J and Kreutzer DL: Cornea-derived neutrophil chemotactic factors: intracellular synthesis and release. **Curr Eye Res** 9(9):839-845, 1990.
25. Allam ME, Houser S, Hashmi F, Liu X, Cordis G and **Elgebaly SA**: Myocardial preservation by cyclocreatine: Restoration of post-ischemic myocardial contractility. **Surg Forum** XLI:246-249, 1990.
26. **Elgebaly SA**, Houser S, El-Kerm AF, Doyel K and Perlman K: Evidence of cardiac inflammation after open heart surgery. **Surg Forum** 41:274-278, 1991.
27. **Elgebaly SA**, Allam ME, Walzak MP and Oselinksy D: Urinary neutrophil chemotactic factors in interstitial cystitis patients and a rabbit model of bladder inflammation. **J Urol** 147:206-211, 1991.
28. **Elgebaly SA**, Hashmi F, Houser S and Allam ME: Cardiac-derived neutrophil chemotactic factors: detection in coronary sinus effluents of patients undergoing myocardial revascularization. **J Thorac Cardiovasc Surg** 103(5):952-959, 1992.
29. **Elgebaly SA**, Allam ME, Houser S, Hashmi F, Forouhar F and Miano D: Cyclocreatine inhibits neutrophil accumulation in the myocardium of a canine model of coronary artery occlusion and reperfusion. **J Pharmacol Exp Therap** 266(3):1670-1677, 1993.

30. **Elgebaly SA**, Gillies C, Shimizu RW, Anger CB, Spencer JA, Buchen SY: Effects of viscoelastic solutions on neutrophil function and the release of neutrophil chemotactic factors from isolated bovine corneas. **Cornea** 3(2):28-34, 1993.
31. **Elgebaly SA**, Houser SL, El-Kerm AF, Doyle K, Gillies C and Dalecki K: Evidence of cardiac inflammation after open heart surgery. **Ann Thorac Surg** 57:35-41, 1994.
32. **Elgebaly SA**, Miano D, Ehler W, Rahhal F and El-Kerm A: The induction of anterior chamber inflammation by factors released from hydrogen peroxide-injured corneas: effect of dexamethasone and indomethacin. **Ocular Pharmacol** 10(1):295-305, 1994.
33. **Elgebaly SA**, Wei Z, Tyles E, El-Kerm AF, Houser SL, Gillies C and Kaddurah-Daouk R: Enhancement of the recovery of rat hearts after prolonged cold storage by cyclocreatine phosphate. **Transplantation** 57(1):1-6, 1994.
34. Shames NBK, Reddy DV, Watanabe K, **Elgebaly SA**, Hanninen LA and Kenyon KR: Increased Interleukin-1 activity in the injured Vitamin A-deficient cornea. **Cornea** 13(2):156-166, 1994.
35. Houser SL, El-Kerm AF, Wei A, Doyle K, Houser D, Tyles E, Kaddurah-Daouk R and **Elgebaly SA**: Enhancement of cardiac function by cyclocreatine in models of cardiopulmonary bypass. **J Mol Cell Cardiol** 27:1065-1073, 1995.
36. **Elgebaly SA**, Lundy J and Goldschneider I: Progenitor T-cell stimulation by induced factors. **FASEB**, 1982.
37. **Elgebaly SA**, Donovan M, Forouhar F, Gillies C, O'Rourke J and Kreutzer DL: Morphologic study of leukocyte-mediated injury to corneal endothelium. **ARVO** (The Association for Research in Vision and Ophthalmology, Inc.), 1983.
38. **Elgebaly SA**, O'Rourke J and Kreutzer DL: Characterization of leukocyte chemotactic factors released by isolated corneas in response to injury (chemical vs. mechanical). *In Vitro Toxicology Symposium*, Johns Hopkins University, Center for Alternatives to Animal Testing, Baltimore, MD, 1986 (invited abstract).
39. **Elgebaly SA**, Kozol RA, Masetti P, Bohr M and Lennon C: The release of neutrophil chemotactic factors from ischemic myocardial tissue. American College of Surgeons (Surgical Forum), San Francisco, CA, October 1987 (presented as a paper; only 20-25% of submitted abstracts are accepted).
40. **Elgebaly SA**, Masetti P and Bohr M: The release of neutrophil chemotactic activity from ischemic coronary artery. Eleventh International Reticuloendothelial Society Meeting, Kawai, Hawaii, 1987.
41. **Elgebaly SA**, Cohen A, Allam M, Yekta N. Cardiac Derived Inflammatory Mediators. **J Mol Cell Cardiol** 21 (11), S 171, 1989.
42. **Elgebaly SA**, El-Kerm AF, Tyles E, El-deeb S and Mauri F: Partial purification of neutrophil chemotactic factors released from peroxide-injured corneas. International Society for Eye Research, Stresa, Italy, September 1991 (invited abstract).
43. **Elgebaly SA**, El-Kerm AF and Laska D: Cornea-derived neutrophil chemotactic factors as predictors of corneal inflammation. International Society for Eye Research, Stresa, Italy, September 1992 (invited abstract).

44. **Elgebaly SA**, House SL, Tyles E, El-Kerm AF, Mauri F and Kreutzer DL: Characterization of a novel small molecular weight neutrophil chemotactic factor human hearts. **Circulation**, 86(4), 1992.
45. **Elgebaly SA**, Tyles E, Houser SL, El-Kerm AF and Mauri F: Partial purification of a novel cardiac-derived neutrophil chemotactic factor: Nourin-1. **Circulation**, 88(4), 1993.
46. Tyles E, Houser SL, Shams N, Consoli K and **Elgebaly SA**: Coronary sinus effluents from cardiopulmonary bypass patients stimulate the secretion of cytokines and adhesion molecules by vascular endothelial cells. **Circulation**, 90(4), 1994.
47. Tyles E, Houser SL, Shams NK, Consoli KA and **Elgebaly SA**: Nourin-1 stimulates the secretion of cytokines by neutrophils: Inhibition by Anti-Nourin-1 Antibody. **Circulation**, 92(8), 1995.
48. **Elgebaly SA**, Tyles E, Houser SL and El-Kerm AF: Cardiac-derived inflammatory mediators. Interscience World Conference on Inflammation, Antirheumatics, Analgesics, Immunomodulators, Geneva, Switzerland, April 1993 (invited abstract).
49. **Elgebaly SA**, Houser SL, El-Kerm A, Houser D, Kaddurah-Daouk R and Tyles E: Myocardial protection by cyclocreatine. Twenty-fourth Cardiac Surgery Meeting, London, England, May 1993 (invited abstract).
50. **Elgebaly SA**, Wei J, El-Kerm AF, Tyles E and Gillies C: Cyclocreatine phosphate significantly improves rat heart function after long-term hypothermic storage. American Society of Transplant Surgeons, Houston, TX, May 1993.
51. **Elgebaly SA**, El-Kerm AF and Tyles E: Cornea-derived inflammatory mediators: new approach to therapy. Pharmacology Society, Novi, MI, August 1993 (invited abstract).
52. **Elgebaly SA**, Tyles E and Kulkarni P: Endotoxin-stimulated release of Nourin-1: A novel 3 kDa cornea-derived chemotactic factor for neutrophils and monocytes. ARVO, Sarasota, FL, May 1994.
53. Tyles E, Kulkarni P and **Elgebaly SA**: Release of neutrophil chemotactic factors from ischemic-injured retinal tissue independent of dexamethasone treatment. ARVO, Sarasota, FL, May 1994.
54. **Elgebaly SA**. The cardiac-derived cytokine Nourin-1: Diagnostic and therapeutic applications. International Symposium on Heart Disease, Cairo, Egypt, May 1998 (invited Speaker).
55. **Elgebaly SA**. The role of infections and inflammation in the pathogenesis of coronary heart disease. 26th annual conference of the Egyptian Society of Cardiology, Cairo, Egypt, February 1999 (invited Speaker).
56. **Elgebaly SA**. Hypertension, Inflammation and coronary heart disease. 26th annual conference of the Egyptian Society of Cardiology, Cairo, Egypt, February 1999 (invited Speaker).
57. **Elgebaly SA**. Hypertension: Pathogenesis & Treatment, Lecture #I. 14th Annual Conference of the Egyptian Society of Hypertension, Cairo, Egypt, January 2000 (invited Speaker).
58. **Elgebaly SA**. Hypertension: Pathogenesis & Treatment, Lecture #II. 14th Annual Conference of the Egyptian Society of Hypertension, Cairo, Egypt, January 2000 (invited Speaker).
59. **Elgebaly SA**. Hypertension and Stroke: Pathogenesis, Diagnosis & Treatment. 15th Annual Conference of the Egyptian Society of Hypertension, Cairo, Egypt, January 2001 (invited Speaker).

60. **Elgebaly SA**, Kreutzer DL: Release of a potent inflammatory mediator from ischemic brain. 27th International Stroke Conference. American heart Association, Austin, Texas, February 2002.
61. **Elgebaly SA**, Kreutzer DL, Mauri F, Azrin M, Fuller R, Christenson R : Nourin-1: an early diagnostic marker for myocardial ischemia and infarction to distinguish cardiac patients from non-cardiac patients presenting in emergency room with chest pain. International Egyptian Society of Cardiology, Alexandria, Egypt, February 2002 (invited Speaker).
62. **Elgebaly SA**. Clinical Trials: “An overall Review”. International Egyptian Society of Cardiology, Alexandria, Egypt, February 2002 (invited Speaker).
63. **Elgebaly SA**. Cardioprotection by cyclocreatine and cyclocreatine phosphate: Overview (in preparation)
64. **Elgebaly SA**. The cardiac-derived neutrophil chemotactic factor, Nourin-1: biochemical & biological overview (in preparation)
65. **Elgebaly SA**. New therapeutic pharmacologic approaches for the treatment of diabetic retinopathy. Retinal Aspen Institute, Aspen Colorado, August 2005 (Invited Speaker by Dr. Bert Glaser)
66. **Elgebaly SA**. Nourin Family: A Novel Therapeutic Target for the Development of Tissue-Specific Anti-Inflammatory Drugs. University of Alexandria Faculty of Pharmacy, Alexandria, Egypt – March 18, 2006 (Invited Speaker).
67. **Elgebaly SA**. Conducting Clinical Research in Egypt: How & FDA Requirements. University of Alexandria Faculty of Medicine, Alexandria, Egypt – March 23, 2006 (Invited Speaker).
68. **Elgebaly SA**. Responsibilities of Clinical Investigators. Cardio Alex 2006, Alexandria, Egypt – June 28, 2006 (Invited Speaker).
69. **Elgebaly SA**. Recruiting and maintaining study patients. Cardio Alex 2006, Alexandria, Egypt – June 29, 2006 (Invited Speaker).
70. **Elgebaly SA**. Nourexin-4: A Novel anti-inflammatory therapy for cardiac inflammation and MRSA infection after cardiac catheterization and surgery. Egyptian Cardiology meeting, Sharm Elsheik, Egypt, February 24-27, 2009 (Invited Speaker).
71. **Elgebaly SA**. Myocardial protection by the anti-apoptotic drug Nourexal. Egyptian Cardiology meeting, Sharm Elsheik, Egypt, February 24-27, 2009 (Invited Speaker).
72. **Elgebaly SA**, Daniel Perez, Kathleen Sullivan, Craig Whitaker, Stephanie Caspe, Qiao Yi, and Donald L. Kreutzer. Nourexin-4: A Novel Anti-inflammatory Therapy for Influenza Flu. American Association of Immunologists Abstract for the May 2010 meeting in Baltimore, Maryland. American Association of Immunologists. May 2010;97:52.
73. **Elgebaly SA**, Christenson R, Schiffmann E, Qiao Yi. and Kreutzer DL. *Early Identification of Cardiac Ischemia Patients in the Emergency Department*. Society for Cardiovascular Angiography and Interventions (SCAI) 2013 Scientific Sessions in Orlando (SCAI). 2013;81:S2-S3.
74. **Elgebaly SA**, Elliott Schiffmann, Ahmed Farghaly, Tamer Elbayoumi, Donald Kreutzer, Cyclocreatine Phosphate is an Effective Cardioprotective Agent against Ischemic Injury. Society for Cardiovascular Angiography & Interventions (SCAI). 2013;84:S1-S2.

75. Christenson R, **Elgebaly SA**: Nourin-1: The "Holy Grail" for Assessing Myocardial Ischemia. *ADVANCE* 16 (1), 19-21, 2004.
76. **Elgebaly SA**. Nourexal: A Novel Anti-inflammatory / Antiapoptotic Therapy Against Reperfusion Injury. *Heart Diseases and Therapeutics. J Clin. Exp. Cardiology*. Vol. 7(9),33,2016.
77. **Elgebaly SA**. Nourexal (Cyclocreatine Phosphate): A New Cardioprotective Therapy Against Reperfusion Injury. *Heart Diseases and Therapeutics. J Clin. Exp. Cardiology*. Vol. 7(11),19-20,2016.
78. **Elgebaly SA**, Elbayoumi T and Kreutzer DL. Cyclosporin H: A Novel Anti-inflammatory Therapy for Influenza Flu Patients. *Journal of the Egypt. Soc. of Parasito*. 2017: 47(1):27-35.
79. **Review Article**
Elgebaly SA, Poston R, Todd R, Helmy T, Almaghraby A, Elbayoumi T, Kreutzer DL.: Cyclocreatine Protects Against Ischemic Injury and Enhances Cardiac Recovery During Early Reperfusion. *Expert Review of Cardiovascular Therapy*, Volume 17(9), 683-697, 2019.

Attachment A

Product Commercialization:

A) Cyclocreatine Phosphate and FDA Orphan Drug Designation

Nour Heart was Granted the Orphan Drug Designation (ODD) by U.S. Food and Drug Administration for its new patented drug Cyclocreatine Phosphate for the unique designation of: ***prevention of ischemic injury to enhance cardiac graft recovery and survival in heart transplantation*** (DRU-2015-4951).

The administration of the potent bioenergetic agent Cyclocreatine and its salt Cyclocreatine Phosphate preserved high levels of myocardial adenosine triphosphate (ATP) in several models of myocardial ischemia resulting in immediate recovery of strong cardiac contractibility during post-ischemic reperfusion. Intact canine models of acute myocardial infarction, cardiopulmonary bypass surgery for coronary revascularization and heart transplantation were used in these studies. Our research also indicates that Cyclocreatine treatment reduced myocardial tissue injury, acidosis, edema, inflammation and apoptosis.

Nour Heart is currently preparing the required ***New Investigational Drug (IND)*** application to file it to the FDA for approval to initiate Phase I clinical studies in the U.S.



The screenshot shows the FDA website's search results for Orphan Drug Designations and Approvals. The search criteria include the generic name 'cyclocreatine phosphate' and the trade name 'Nourexal'. The results table provides the following details:

Generic Name:	cyclocreatine phosphate
Trade Name:	Nourexal
Date Designated:	01/17/2018
Orphan Designation:	Prevention of ischemic injury to enhance cardiac graft recovery and survival in heart transplantation.
Orphan Designation Status:	Designated
FDA Orphan Approval Status:	Not FDA Approved for Orphan Indication
Marketing Approval Date:	N/A
Approved Labeled Indication:	
Exclusivity End Date:	N/A
Sponsor:	Nour Heart Therapeutics, LLC 121 Locust Street, SW Vienna, Virginia 22180 USA

The sponsor address listed is the last reported by the sponsor to OOPD.

B) Cardiac Nourin Blood Test

Nourin is a potent inflammatory mediator rapidly released within minutes by ischemic and necrotic myocardium. Nourin can diagnose AMI patients ***earlier*** than Troponins and it can also diagnose ACS patients (UA and AMI) presenting to Emergency Departments with chest pain. Currently, Nour Heart is developing the Nourin test to ***complement*** and ***enhance*** the usefulness of the Troponin tests to quickly ***rule in or out*** AMI patients presenting with chest pain in Emergency Departments.

Attachment B

Clinical Research and Trial Expertise:

Expertise in National and International Biomedical Industrial Field in:

- Industrial Drug Development (R&D);
- Industrial Clinical Research and FDA submissions;
- FDA regulations & guidelines;
- Clinical Trials conducted in Investigative Sites; and
- International experience in:
 - Europe (United Kingdom)
 - Europe (Holland)
 - Japan
 - China
 - Egypt.

Industrial R&D & Clinical Research Experience:

As a Director of Clinical Research in the start-up biotech company Nour Heart, Germantown, MD the goal is to develop diagnostic and therapeutic products for patients with ischemic heart disease. As a Director of Clinical Affairs in the Biotech Company AnGes, Gaithersburg, MD and a Consultant Director of the Nourin project in the company Unipath, Bedford, UK, we focused our efforts at also developing diagnostic and therapeutic products in the field of cardiovascular diseases.

Clinical Research Activities Included:

- Designing and writing study protocols;
- Supervising preclinical efficacy studies in U.S., Europe, Japan and China;
- Evaluating study results;
- Filing IND to FDA;
- Responding to FDA questions;
- Selecting CROs and assuring timely completion of clinical studies within budget;
- Selecting Investigative Sites and conducting Investigators Meetings.

Clinical Trials Experience:

I established two new Clinical Trials & Research Centers in Connecticut:

- Connecticut Multispecialty Group and
- Grove Hill Medical Center

As a Director of these Clinical Trials & Research Centers, the following activities were conducted:

- Reviewed study protocols and selected clinical studies for our centers;
- Reviewed confidentiality agreements;
- Discussed study protocols and Investigative Brochures with Investigators and study Coordinators;
- Completed FDA regulatory documents as well as local & central Institutional Review Board (IRB) submissions;
- Functioned as a sub-Investigator in all clinical studies and attended each study Investigators Meetings;
- Negotiated study budgets and contracts;
- Supervised Clinical Research Coordinators;
- Assured that the Investigators and study Coordinators comply with study protocol, GCP guidelines, and FDA regulations;
- Assured that patients' safety and confidentiality were met;
- Communicated with Investigators, study Coordinators, and Sponsors regarding adverse events and patients' progress;

- Assured timely patients' recruitments and that all visits' requirements were conducted timely and properly;
- Internally monitored over 26 clinical studies (Phase II, Phase III, and Phase IV) in the field of Oncology, Cardiovascular, infections, Psychiatry, Pulmonary, Rheumatoid Arthritis, Diabetes, Erectile Dysfunction, Surgery, Gene Analysis, etc.

International Clinical Research Experience:

- *United Kingdom and China:* As a Consultant Director of the Nourin project in Unipath, Bedford, UK, I worked closely with the R&D Department in Bedford, UK, as well as its branch in China.
- *Holland and Japan:* As a Director of Clinical Affairs in AnGes, I worked closely with the R&D Department in Japan and established Preclinical efficacy studies in Holland.
- *Egypt:* I established a new Clinical Trials & Research Center at the University of Alexandria School of Medicine and I currently function as a volunteer Consultant in aspect related to Drug Testing and Clinical Trials.

