

令和4年8月3日

## ミトコンドリア投与を行う臨床試験についての実態

### - NIHClinicaltrial の調査

1. NIHClinicaltrial に投稿されているミトコンドリア投与を行っている臨床試験について調べてみた。10 を超える臨床試験が実施されている模様（表参照）、全てが調査できているわけではない
2. 臨床研究で投与されているミトコンドリアは自己、同種、同種カクテル製品がある
3. 少なくとも先進国で承認されているミトコンドリア製品はない
4. 対象疾患は様々であるが、国内ミトコンドリア学会である「日本ミトコンドリア学会」(<https://www.j-mit.org/>) でも検討が進められている  
(ア) 主として小児神経疾患の専門医が主なメンバーであることから、小児神経疾患についての項目を下記に記載
5. NIHClinicaltrial で対象とされている疾患等  
(ア) 小児ミトコンドリア移植対象疾患
  - ① Deoxyguanosine kinase deficiency
  - ② Mitochondrial complex I deficiency
  - ③ Childhood myocerebrohepatopathy spectrum
  - ④ Mitochondrial neurogastrointestinal encephalopathy disease
  - ⑤ Mitochondrial complex V deficiency
  - ⑥ Autism spectrum disorder
  - ⑦ Ataxia neuropathy spectrum
  - ⑧ Myoclonic epilepsy myopathy sensory ataxia  
(イ) これら以外にヒト胚、湾岸戦争後遺症、なども挙げられている。

The KHENEREXT Study	<b>Mitochondrial Diseases</b>	Drug: Oral <b>administration</b> of 100 mg KH176 twice daily	Rigshospitalet, University of Copenhagen
<u>Does Clinical Treatment of Mitochondrial Dysfunction Impact Autism Spectrum Disorder (ASD)?</u>	Autism Spectrum Disorders  <b>Mitochondrial Diseases</b>	Drug: <b>Mitochondrial</b> Cocktail	St. Christopher's Hospital for Children  Philadelphia, Pennsylvania, United States
<u>Autologous Mitochondrial Transfer in ICSI to Improve Oocyte and Embryo Quality in IVF Patients. Pilot Study</u>	Infertility	Other: Autologous <b>mitochondria</b> with ICSI  Other: STANDARD ICSI PROCEDURE	IVI Valencia  Valencia, Spain
<u>Mitochondrial Cocktail for Gulf War Illness</u>	Gulf War Syndrome  Persian Gulf Syndrome	Dietary Supplement: Individualized <b>mitochondrial</b> cocktail  Dietary Supplement: Placebo	UC San Diego  La Jolla, California, United States

	<b>Mitochondrial</b> Disorders		
<a href="#"><u>Mitochondria-targeted System Therapy Combined With Radiofrequency Ablation for Early-stage Non-small Cell Lung Cancer</u></a>	Non Small Cell Lung Cancer	Other: <b>Mitochondria</b> -targeted System Therapy Combined With Radiofrequency Ablation Procedure: Surgery	Shanghai 10th People's Hospital  Shanghai, Shanghai, China
<a href="#"><u>The Effects of a Regenerative Mitochondrial Medication on Physiological Parameters in Case of Diabetes Mellitus Type II</u></a>	Diabetes Mellitus, Type II	Dietary Supplement: <b>Mitochondrial</b> preparations  Dietary Supplement: Infusion therapy Device: Webermedical device Behavioral: Nutritional therapy	CFI Centrum für Integrative Medizin  Speyer, Germany
	Cerebral Ischemia		Harborview Medical Center

<a href="#"><u>Autologous Mitochondrial Transplant for Cerebral Ischemia</u></a>		Other: Endovascular autologous <b>mitochondrial</b> transplantation	Seattle, Washington, United States
<a href="#"><u>Transplantation of Autologously Derived Mitochondria Following Ischemia</u></a>	Extracorporeal Membrane Oxygenation Complication	Other: autologous <b>mitochondria</b> transplantation	Boston Children's Hospital Boston, Massachusetts, United States
<a href="#"><u>Clinical Application of Autologous Mitochondria Transplantation for Improving Oocyte Quality.</u></a>	Repetition Failure	Procedure: autologous <b>mitochondria</b> transplantation  Combination Product: autologous <b>mitochondria</b> from bone marrow mesenchymal stem cells into oocyte as well as intracytoplasmic sperm injection (ICSI)  Drug: intracytoplasmic sperm injection (ICSI)	
	Low Ovarian Reserve	Procedure: Injection of an autologous <b>mitochondria</b> to the oocyte.	Hadassah University Hospital

Improving the Reproductive Outcome of  
Poor Quality Ova by Injection of Autologous  
Somatic Mitochondria

Poor Quality Oocytes

Jerusalem,  
Israel