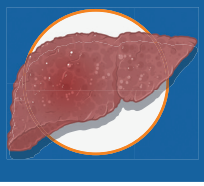
EMMPOWER℠
OHE CLINICAL TRIAL

NOW RECRUITING: PHASE 2 CLINICAL TRIAL

Have you or a loved one been diagnosed with OHE?

(OVERT HEPATIC ENCEPHALOPATHY)

You or your loved one could be eligible to participate in a clinical trial of an investigational treatment for OHE.



OHE is a serious medical condition that affects how the brain and nerves work. People with OHE can become very confused and may be unable to care for themselves. This condition can lead to hospitalization, coma and even death.

About the EMMPOWER Phase 2 Clinical Trial in Subjects Who Have Experienced OHE

EMMPOWER (#NCT04816916) is being conducted to investigate the effectiveness and safety of AXA1665, an investigational (not approved) new drug that is administered as a drink for subjects who have recently experienced an OHE episode.

EMMPOWER will seek to determine if AXA1665 is able to reduce the risk of OHE episodes and improve thought processing in subjects who have a history of OHE. Additionally, the trial will investigate AXA1665's potential to prevent muscle loss and improve the ability to perform physical activities without assistance.

The trial compares AXA1665 versus a placebo over a 24-week study treatment period and a four-week safety follow-up period. Approximately 150 subjects are being enrolled across more than 70 clinical sites worldwide.

Trial sponsored by axcella

Subjects who participate in EMMPOWER will be able to continue taking their current OHE treatments (lactulose and/or rifaximin) and will receive:

AXA1665 for 24 weeks if assigned to the active study drug (half of subjects to receive active study drug)

Trial-related monitoring and care from a physician who has experience with cirrhosis and OHE

Trial-related medical tests

TO BE INCLUDED IN EMMPOWER, SUBJECTS MUST:

- Be at least 18 years of age
- Have a history of cirrhosis and at least one documented OHE episode within the past 6 months
- Have a caregiver who is able to support them during the trial

SUBJECTS WILL BE EXCLUDED FROM EMMPOWER IF THEY:

- Have other serious complications of cirrhosis (i.e., kidney failure, fluid retention in the stomach, infection)
- Have other neurologic conditions, such as Alzheimer's disease or Parkinson's disease
- Drink excessive alcohol

If you or your loved one might want to participate, you should ask your doctor or one of the clinical trial sites about whether EMMPOWER is right for you.

See pg. 5 for a listing of clinical trial sites

About OHE

OHE is a serious medical condition that affects how the brain and nerves work. People with OHE can become confused to the point where they are unable to care for themselves. This condition can lead to hospitalization, coma and even death.

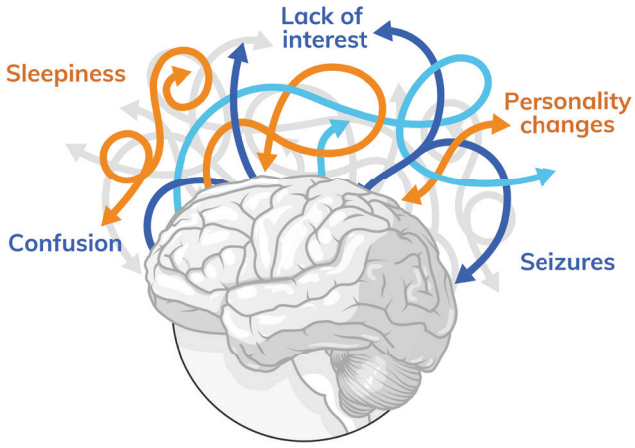
OHE results from an advanced liver disease called cirrhosis. The human liver plays an essential role in filtering toxins, such as ammonia, out of the bloodstream. In patients with cirrhosis, toxins build up in the body and travel to the brain, impairing thinking and causing confusion, among a host of other symptoms. Additionally, many patients with cirrhosis experience muscle wasting (known as sarcopenia) that can be rapid and severe as the muscle tries to help clear toxins from the body.

It is estimated that up to 50% of patients with cirrhosis will develop hepatic encephalopathy. This can range from a milder form of the condition, known as minimal or covert hepatic encephalopathy, to the most severe and apparent form, known as overt hepatic encephalopathy (OHE). While OHE usually lasts for a period of hours or days, patients can experience frequent episodes, and they tend to be impaired to the point where they are unable to care for themselves and often must be hospitalized.

Currently, there are limited medications approved for OHE. Even when taking these therapies, many patients continue to experience breakthrough OHE episodes.

SYMPTOMS OF OHE

- Confusion
- Lack of energy, attention and interest
- Significant personality changes
- Sleepiness
- Seizures
- Shaking hands
- Worsened handwriting
- Breath that smells musty or sweet



About AXA1665

AXA1665 is a proprietary mixture of eight amino acids, which are small molecules that make up the building blocks of proteins in the body. Amino acids are a normal part of the human diet and naturally influence many of the body's systems.

AXA1665 is a dry powder agent that is simply mixed with a small amount of water and drank by the subject. The EMMPOWER trial is seeking to determine this product candidate's ability to work with the body's system to improve thinking, reduce OHE events, and improve muscle function in subjects who have a history of OHE. The trial also will investigate safety and tolerability versus a placebo.

SCAN CODE TO LEARN MORE ABOUT
EMM Compositions for Complex Diseases

To learn more about what clinical trials are and what it is like to be enrolled in one, visit:

World Health Organization:
www.who.int/health-topics/clinical-trial

Clinicaltrials.gov:
clinicaltrials.gov/ct2/about-studies/learn

Participate

The following clinical sites are now actively participating in the EMMPOWER trial:

Country	Site Primary Address	Site Name/Contact
United States	350 Parnassus Avenue San Francisco, CA 94117	**University of California, San Francisco (UCSF)** ph: 415-353-2318
United States	70 Spring Vista Drive Debary, FL 32713	**Omega Research** ph: 386-668-4202
United States	1600 SW Archer Road Gainesville, FL 32608	**UF Hepatology Research at CTRB** ph: 352-273-9400
United States	27535 South Dixie Highway Miami, FL 33032	**Homestead Associates in Research** ph: 305-246-0873
United States	1500 Northwest 12th Avenue #1101 Miami, FL 33136	**University of Miami - Schiff Center for Liver Diseases** ph: 305-243-4615
United States	200 Hawkins Drive Iowa City, IA 52242	**University of Iowa** Ph:319- 356-2132
United States	355 West 16th Street Suite 3222 Indianapolis, IN 46202-2267	**Indiana University (IU) School of Medicine** ph: 317-274-8157
United States	345 St. Paul Place Baltimore, MD 21202	**Mercy Medical Center** ph: 410-332-9356
United States	2109 Valleygate Drive Suite 102 Fayetteville, NC 28304	**Cumberland Research Associates** ph: 910-484-8163
United States	NYU Langone Health, 550 First Avenue New York, NY 10016	**New York University (NYU) School of Medicine** ph :212-263-3643
United States	1283 York Avenue; 9th Floor New York, NY 10065	**Weill Medical College of Cornell University** ph: 212-746-2127
United States	1218 Scaife Hall, 3550 Terrace Street Pittsburgh, PA 15261	**University of Pittsburgh Medical Center** ph: 412-647-7922
United States	96 Jonathan Lucas Street Charleston, SC 29425	**Medical University of South Carolina (MUSC)** ph: 843-792-2914
United States	1608 Saint Claire Avenue Edinburg, TX	**Optimed Research** ph: 956-284-6353
United States	1400 8th Avenue Fort Worth, TX 76104	**Baylor Scott & White Research Institute** ph: 817-926-2544
United States	6620 Main Street #1505 Houston, TX 77030	**Advanced Liver Therapies at St. Lukes Episcopal Hospital** ph: 713-798-1966
United States	5109 Medical Drive Suite 200 San Antonio, TX 78229	**Pinnacle Clinical Research** ph: 210-982-0320
United States	1300 Jefferson Park Avenue MSB Second Floor 2266-2243 Charlottesville, VA 22908-2877	**University of Virginia School of Medicine** ph: 434-243-3090

Participate

The following clinical sites are now actively participating in the EMMPOWER trial:

United States	12720 McManus Blvd Suite 313 Newport News, VA 23602	**Bon Secours Liver Institute of Newport News** ph: 757-947-3190
United States	1101 East Marshall Street Richmond, VA 23298-0160	**Virginia Commonwealth University** ph: 804-828-4060
United States	1201 Broad Rock Boulevard Richmond, VA 23249	**McGuire Research Institute, Inc./McGuire VA Medical Center** ph: 804-675-5021
Canada	Health Sciences Centre 3330 Hospital Drive NW Calgary, Alberta T2N 4N1 Canada	**University of Calgary** ph: 1-403-944-6516
Canada	230 Victoria Street Suite 226 London, Ontario L6A 2C2 Canada	**LMC Diabetes & Endocrinology Ltd. - London** ph: 1-833-323-JOIN
Canada	501 Smyth Box 511 Ottawa, Ontario K1H 8L6	**The Ottawa Hospital** ph: 613-761-4295
Hungary	Debrecen, Nagyerdei krt. 98, 4032 Hungary	**Debreceni Egyetem Klinikai Kozpont** ph: +36 52 411 600
Hungary	Fejer Megyei Szent Gyorgy Egyetemi Oktato Korhaz	**Székesfehérvár, Hunyadi u. 2, 8000 Hungary** ph: +36 22 535 540
Poland	Janowska 19, 41-400 Mysłowice, Poland	**ID Clinic** ph: +48 32 616 13 94
Poland	Józefa Sierakowskiego 4/lok.U3, 03-712 Warszawa, Poland	**Prywatna Specjalistyczna Praktyka Lekarska Jan Gietka** ph: +48 22 826 11 60
Poland	4, Jana Długosza, 51-162 Wrocław, Poland	**Centrum Badan Klinicznych Piotr Napora Lekarze Sp. p.** ph: +48 71 326 79 00
Poland	Medical Center Sonomed, księdza Biskupa Władysława Bandurskiego 98, 71-685 Szczecin, Poland	**SONOMED Sp. z o.o.** ph: +48 91 820 11 10
Spain	Rúa da Choupana, s/n, 15706 Santiago de Compostela, A Coruña, Spain	**Hospital Clinico Universitario de Santiago** ph: +34 981 95 00 00
Spain	Passeig de la Vall d'Hebron, 119, 08035 Barcelona, Spain	**Hospital Universitario Vall d'Hebron** ph: +34 934 89 30 00
Spain	Parc Taulí, 1, 08208 Sabadell Barcelona, Spain	**Corporacio Sanitaria Parc Tauli - Hospital de Sabadell** ph: +34 937 23 10 10
Spain	Av. de Valdecilla, 25, 39008 Santander Cantabria, Spain	**Hospital Universitario Marques de Valdecilla** ph: +34 942 20 25 20
Spain	Av. Manuel Siurot, S/n, 41013 Sevilla, Spain	**Hospital Universitario Virgen del Rocio** ph: +34 955 01 20 00
United Kingdom	51 Little France Cres, Old Dalkeith Rd, Edinburgh EH16 4SA, United Kingdom	**The Royal Infirmary of Edinburgh** ph: +44 131 536 1000