Hyperbare Hochdruck–Sauerstofftherapie beim Post–COVID–Syndrom und ME/CFS

ClinicalTrials.gov-ID NCT06118138

Sponsor Charité–Universität, Berlin, Deutschland

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Studiendetails Tab

Studienübersicht

Kurze Zusammenfassung

Das Ziel dieser Beobachtungsstudie ist es, den Symptomverlauf bei 60 Patienten mit myalgischer Enzephalomyelitis/chronischem Erschöpfungssyndrom (ME/CFS) zu dokumentieren, die sich einer hyperbaren Sauerstofftherapie unterziehen (HBOT) nach COVID oder anderen Infektionen. Die Teilnehmer erhalten HBOT Behandlung als zusätzliche Option nach Abschluss der Chronic Fatigue Syndrome CARE (CFS_CARE)–Studie und werden zur Teilnahme an dieser Beobachtungsstudie eingeladen. Die Patienten werden Gesundheitsbewertungen in Form von Fragebögen ausfüllen, darunter den 36–Item Short Form Health Survey (SF–36), um Veränderungen der ME/CFS–bezogenen Symptome nach HBOT Anstatt die Wirksamkeit von HBOT Die Studie selbst konzentriert sich auf die Beobachtung und Dokumentation dieser Veränderungen. Ihr Ziel ist es, wertvolle Einblicke in den Symptomverlauf bei ME/CFS–Patienten zu geben, die HBOT, die als Grundlage für zukünftige interventionelle randomisierte kontrollierte Studien dienen können.

Detaillierte Beschreibung

Nach einer leichten bis mittelschweren COVID–Infektion entwickeln etwa 10% der Betroffenen ein Post–COVID–Syndrom (PCS), das durch Symptome wie Müdigkeit, Belastungsintoleranz, kognitive Beeinträchtigung, Kopfschmerzen und Muskelschmerzen gekennzeichnet ist (Kedor et al., 2022). Bei einigen PCS–Patienten kann später ME/CFS diagnostiziert werden, eine schwere und chronische Erkrankung, die durch Infektionen ausgelöst wird (Renz–Polster & Scheibenbogen, 2022). ME/CFS weist Symptome wie lähmende Müdigkeit, Belastungsintoleranz, postexertionales Unwohlsein (PEM), Kopfschmerzen, Muskelschmerzen, kognitive Beeinträchtigung („Gehirnnebel"), orthostatische Intoleranz, autonome Dysfunktion, Schlafstörungen und ein allgemeines

Krankheitsgefühlauf.Derzeitgibtes keine kurative Therapie fürME/CFS.Die Therapieverfahren für ME/CFS konzentrieren sich hauptsächlich aufdas Symptommanagement,aberaufgrundderhohen Patientenzahlund derAuswirkungen aufdas Gesundheitswesen sind evidenzbasierteund standardisierte Behandlungen dringend erforderlich (Renz-Polster& Scheibenbogen,2022). Es werden Off-Label-Medikamenten–und nicht-medikamentöse Ansätze verwendet,fürderen Wirksamkeites jedochkeine ausreichenden Belege aus kontrollierten Studien gibt.

ME/CFS and PCS mayhave differentunderlying pathomechanisms,with some patients showing endothelialdysfunction and reduced bloodflow (Haffke etal.,2022).Enhancing bloodflow and promoting the formation ofnew capillaries is a potentialtherapeutic approach due to the presumed role of reduced bloodflow.In this regard,Hyperbaric OxygenTherapy (HBOT)is underinvestigation as a treatmentforME/CFS and PCS,showing promising results in trials (e.g.,Zilberman-Itskovich et al.,2022;Robbins etal.,2021;Kjiellberg etal.,2022;Akarsuetal.,2013).This non-interventional observationalstudy aims to documentsymptom progression in 60 patients with ME/CFS who underwentHBOT following COVIDorotherinfections.The study does notfocus on evaluating the efficacy ofHBOT itself.

ME/CFS patients currently participating in the Chronic Fatigue Syndrome CARE (CFS_CARE)study at KlinikBavariain Kreischa willhave the opportunity to receive HBOT treatmentas a supplementary offerfrom the clinic upon completion ofthe CFS_CARE study.Additionally,these patients willbe invited to participate in this observationalstudy during thefinalCFS_CARE presentation atthe 12-monthmark.HBOT is performedas partofthe ConformitéEuropéenne (CE)certificate,as an outpatientprocedure within standard clinicalpractice,and independentofthe study focus. Throughoutthe HBOT treatment,patients willundergo health assessments and symptom evaluations fourweeks aftertreatmentinitiation and fourweeks aftercompleting the HBOT sessions.To facilitatethis,patients willreceive a link to a RedCapfile containing questionnaires, includingthose previouslyutilized in the CFS_CARE study (36-Item ShortForm HealthSurvey (SF-36),Munich Berlin Symptom Questionnaire (MBSQ),ChalderFatigue Questionnaire,BellScore). Completing the questionnaires typically requires approximately 45 minutes.The questionnaires will be collectedeverytwo monthsover12 months,resulting in a totalfollow-up period of10 months.A follow-up visitatthe outpatientclinic is scheduled forfourweeks afterHBOT is completed.

The study's primary endpointis to identify improvements in physicalfunction following HBOT.This willbe achieved byutilizingthe SF-36 PhysicalFunction (PF)questionnaire,which commonlyserves as theprimary endpointin clinicaltrials focusedon ME/CFS.Ithas beenshownthatan increase of atleast10 pointsin the SF-36 PF (range 0 -100 = healthy) defines clinically relevantimprovement ("a little better"),and an increase of20 points defines greaterclinicalimprovement("much better") (Brigden 2018).Therefore,an increaseofatleast10 points 4 weeks afterHBOT is definedas a response and assessed as the primary endpoint.

Die studienbezogenenMaßnahmen stellen fürdie Teilnehmer,abgesehen vom Zeitaufwand fürdas AusfüllenderFragebögen,keine nennenswerten Risiken oderzusätzlichen Belastungen dar. Sie birgt jedoch das Potenzial,wertvolle Erkenntnisse überHBOT als mögliche Behandlung von ME/CFS zu gewinnen.Bishergibtesleine Dokumentation derWirksamkeitvon HBOT beiME/CFS durch eine klinische Studie mitobjektiven Methoden.Die Ergebnisse dieserBeobachtungsstudie sollen als Grundlage füreine mögliche interventionelle randomisierte kontrollierte Studie (RCT)dienen.

Offizieller Titel

Beobachtungsstudie zurhyperbaren Hochdruck-Sauerstofftherapie (HBOT)beiPatientenmitPost-COVID-Syndrom (PCS)undMyalgische Enzephalomyelitis/chronisches Erschöpfungssyndrom(MICH/CFS)

Bedingungen

Nach COVIDMICH/CFS

Intervention /Behandlung

- Combination Product:Hyperbaric oxygen therapy (HBOT)

Andere Studien-ID-Nummern

- HBOT
- 01EP2201(OtherGrant/Funding Number)(OTHER_GRANT:BMBF)

Studienbeginn (Tatsächlich)

15.07.2023

PrimärerAbschluss (Geschätzt)

31.12.2025

Studienabschluss (Geschätzt)

31.12.2025

Einschreibung (Geschätzt)

60

Studientyp

Beobachtung

Ressourcenlinks derNationalLibrary ofMedicine

MedlinePlus (https://medlineplus.gov/)Verwandte Themen: Ermüdung (https://medlineplus.gov/fatigue.html)
Myalgische Enzephalomyelitis/Chronisches Erschöpfungssyndrom (https://medlineplus.gov/myalgicencephalomyelitischronicfatiguesyndrome.html)
Sauerstofftherapie (https://medlineplus.gov/oxygentherapy.html)

Informationszentrumfürgenetische und seltene Krankheiten (https://rarediseases.info.nih.gov/gard)Ressourcen: Chronische Graft-versus-Host-Krankheit (https://rarediseases.info.nih.gov/diseases/10964/chronic-graft-versus-host-disease)

FDA-Ressourcen zu Arzneimitteln und Geräten (https://clinicaltrials.gov/fda-links)

Kontakte und Standorte

In diesem Abschnitt finden Sie Kontaktdaten von Personen, die Fragen zur Teilnahme an dieser Studie beantworten können, sowie Informationen darüber, wo diese Studie stattfindet.

Weitere Informationen finden Sie im Abschnitt „Kontakte und Standorte“ in „So lesen Sie einen Studienbericht“ (https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations).

Studienkontakt

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Diese Studie hat 1 Standort

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Teilnahmekriterien

Forscher suchen nach Menschen, die einer bestimmten Beschreibung entsprechen, genannt Zulassungskriterien. Beispiele für diese Kriterien sind der allgemeine Gesundheitszustand einer Person oder frühere Behandlungen.

Allgemeine Informationen zur klinischen Forschung finden Sie unter „Informationen zu Studien“ (https://clinicaltrials.gov/study-basics/learn-about-studies).

Teilnahmekriterien

Beschreibung

Einschlusskriterien:

- Teilnehmerim Alterzwischen 18 und 65 J ahren,die bereits an derCFS_CARE-Studie teilgenommenhaben und beidenen ME/CFS diagnostiziertwurde
- ME/CFS-Diagnose basierend aufden Canadian Consensus Criteria (CCC), gekennzeichnetdurch Belastungsintoleranz und Symptomverschlechterung,die mindestens 14 Stunden anhält
- Disease severity determined by a Bell Score ranging from 30 to 70
- Plan to undergo 20 or 40 days ofHyperbaric OxygenTherapy (HBOT)
- Consentprovided by the patient

Exclusion Criteria:

- Unwillingness to consentto the storage ofpseudonymized clinicaldata as a partofthe study
- Pregnancy
- Presence ofmedicalconditions thatcould potentially pose a risk during Hyperbaric OxygenTherapy (HBOT)(e.g.,heartfailure,pulmonary disease,majordepression,panic attacks)
- Acute infection (e.g.,COVID,HIV,orhepatitis)

Study Population

Sixty male orfemale patients,aged between 18 and 65 years,willbe included in the study. ME/CFS patients currently participating in the CFS_CARE study through the Bavaria Clinic in K reischa willhave the opportunity to receive HBOT treatmentas an additionaloption provided bythe clinic upon completionofthe CFS_CARE study.Additionally,these patients willbe invited to participate in this observationalstudy during the finalCFS_CARE presentation atthe 12-month mark.

Ages Eligible forStudy

18 Years to 65 Years (Adult, OlderAdult)

Sexes Eligible forStudy

All

Accepts Healthy Volunteers

No

Sampling Method

Non-Probability Sample

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Observational Model ⓘ : Cohort
Time Perspective: Prospective

Groups and Interventions

Intervention/Treatment ⓘ
Combination Product: Hyperbaric oxygen therapy (HBOT) • HBOT is a medical treatment employed for various conditions. It entails breathing 100% oxygen within a pressurized chamber known as a hyperbaric chamber. This oxygen-rich environment promotes healing and aids in combating specific infections. In this study, the investigators will administer HBOT using a hyperbaric chamber set to 2 times the normal atmospheric pressure, indicated as 2 atmosphere absolute (ATA). This pressure surge enhances oxygen dissolution into the bloodstream, surpassing levels achievable at sea level. The pressure will be raised incrementally, followed by HBOT sessions lasting for a total of 90 minutes. The 90-minute sessions include brief 5-minute intervals for ambient air every 20 minutes to ensure safety and comfort. Treatment will be conducted five days a week over eight weeks. Supervised by competent healthcare professionals, HBOT is considered safe, with potential side effects primarily stemming from heightened pressure and, in rare cases, oxygen toxicity.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Improvement in Physical Function (PF) as measured by the Short Form 36 Health Survey Questionnaire (SF-36).	The Short Form 36 Health Survey (SF-36) is an established and widely used health-related quality of life measure. The Physical Function (PF) domain asks patients to report limitations on ten mobility activities, such as walking specified distances, carrying groceries, and bathing or dressing. Scores are weighted and transformed into a scale ranging from 0 (greatest possible health restrictions, i.e., severe disability) to 100 (no health restrictions). An intra-patient change of 10 points in SF-36-PF from baseline to week four is considered clinically meaningful.	4 weeks after completion of HBOT therapy

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Duration of improvement in Physical Function (PF) as measured by the Short Form 36 Health Survey Questionnaire (SF-36)	Duration of the effect of HBOT therapy as assessed by SF-36 PF. Intra-patient change in physical and mental fatigue from baseline to follow-up points will be documented as indexed by the SF-36 PF.	Collected every 2 months over a total of 12 months after completion of HBOT therapy

Improvement in physical and mental fatigue as measured by the Chalder Fatigue Scale	The Chalder Fatigue Scale measures the extent and severity of tiredness and has been used in multiple randomized trials of behavioral interventions in patients with ME/CFS. Each of the 11 items is answered on a 4-point scale with an overall score ranging from 0 (asymptomatic) to 33 (maximum symptomology). Intra-patient change in physical and mental fatigue from baseline to follow-up points will be documented as indexed by the Chalder Fatigue Scale.	Collected every 2 months over a total of 12 months after completion of HBOT therapy
Improvement in functional disability as measured by the Bell disability scale	The Bell disability scale is a standard assessment in ME/CFS that evaluates functional ability in adult ME/CFS patients. Eleven statements describe patient status such as level of symptoms at rest, level of symptoms with exercise, activity level, and ability to perform work, travel and self care. Its score ranges from 0 (bedridden) to 100 (no symptoms). Intra-patient change from baseline to follow-up points will be documented as indexed by the Bell score.	Collected every 2 months over a total of 12 months after completion of HBOT therapy
Improvement in disease severity based on self-reported symptoms as measured by the Munich Berlin Symptom Questionnaire (MBSQ)	The Munich Berlin Symptom Questionnaire (MBSQ) is a questionnaire for ME/CFS that captures the Institute of Medicine (IOM) and Canadian Consensus Criteria (CCC) as well as a total of 44 symptoms from 8 domains on a scale of 0 – 4 for frequency and severity. From this, a score for total symptom severity ranging from 0 (not present) to 352 (very severe) is calculated. Intra-patient change from baseline to follow-up points will be documented as indexed by the MBSQ.	Collected every 2 months over a total of 12 months after completion of HBOT therapy

Improvement in muscle strength as measured by the hand grip strength (HGS) test	The Hand Grip Strength (HGS) test is a simple yet effective measurement of muscular strength. It involves gripping a dynamometer (or other grip strength measurement device) with maximal force using the dominant hand. The device measures exerted force in kilograms or pounds. Hand grip strength reflects overall muscle strength providing insights into a person's physical health, functional capacity, and potential muscular deficiencies. Intra-patient change in hand grip strength (HGS) from baseline to week four.	4 weeks after completion of HBOT therapy
Assessment and documentation of tolerability	Assessment and documentation of tolerability with a questionnaire that is collected at the end of the HBOT therapy	On the day of completion of HBOT therapy
Improvement in orthostatic tolerance as measured by the National Aeronautics and Space Administration (NASA) 10 Minute Lean Test	The NASA 10-Minute Lean Test evaluates a person's susceptibility to gravitational effects. In post-COVID ME/CFS research, it probes cardiovascular and autonomic nervous system issues stemming from a SARS-CoV-2 infection. During the test, an person lies flat on their back with a slightly elevated head, while blood pressure and heart rate are monitored during a controlled tilt to a head-down position. In about 10 minutes, this provides valuable insights into cardiovascular adaptability and potential dysregulation, aiding understanding of symptoms like dizziness, fatigue, and palpitations in long-COVID patients. Intra-patient change in the NASA 10 Minute Lean Test from baseline to week four.	4 weeks after completion of HBOT therapy

Improvement in exercise capacity measured by the 1-Minute Sit-to-Stand Test	The 1-Minute Sit-to-Stand Test is a validated and reliable test for quantifying exercise capacity. In this test, the person starts in a seated position and is instructed to stand up and sit down as many times as possible within a one-minute period. The test provides valuable insights into a person's muscle strength, endurance, and overall physical fitness. Intra-patient change in the 1-minute Sit-to-Stand Test from baseline to week four.	4 weeks after completion of HBOT therapy

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Charite University, Berlin, Germany

Collaborators

- KLINIK BAVARIA Kreischa
- Vivantes Klinikum im Friedrichshain

Investigators

- Principal Investigator: Carmen Scheibenbogen, Prof. Dr., Charite University, Berlin, Germany

Publications

General

These publications are provided voluntarily by the person who enters information about the study and may be about anything related to the study.

- Kedor C, Freitag H, Meyer-Arndt L, Wittke K, Hanitsch LG, Zoller T, Steinbeis F, Haffke M, Rudolf G, Heidecker B, Bobbert T, Spranger J, Volk HD, Skurk C, Konietschke F, Paul F, Behrends U, Bellmann-Strobl J, Scheibenbogen C. A prospective observational study of post-COVID-19 chronic fatigue syndrome following the first pandemic wave in Germany and biomarkers associated with symptom severity. Nat Commun. 2022 Aug (https://pubmed.ncbi.nlm.nih.

30;13(1):5104.doi:10.1038/s41467-022-32507-6.Erratum In:NatCommun.2022 Oct 12;13(1):6009.doi:10.1038/s41467-022-33784-x. (https://pubmed.ncbi.nlm.nih.gov/36042189)

- Renz-PolsterH,ScheibenbogenC.[Post-COVIDsyndrome with fatigue and exercise intolerance:myalgic encephalomyelitis/chronic fatigue syndrome]. Inn Med (Heidelb).2022 Aug;63(8):830839.doi:10.1007/s00108-022-01369-x. Epub 2022Jul13.German. (https://pubmed.ncbi.nlm.nih.gov/35925074)

- Haffke M,FreitagH,RudolfG,SeifertM,DoehnerW,Scherbakov N,Hanitsch L, Wittke K,BauerS,Konietschke F,PaulF,Bellmann-StroblJ,KedorC,Scheibenbogen C,SotznyF.Endothelialdysfunction and altered endothelialbiomarkers in patients with post-COVID-19 syndrome and chronic fatigue syndrome (ME/CFS).J Transl Med.2022 Mar22;20(1):138.doi:10.1186/s12967-022-03346-2. (https://pubmed.ncbi.nlm.nih.gov/35317812)

- Zilberman-Itskovich S,CatalognaM,Sasson E,Elman-Shina K,Hadanny A,Lang E, FinciS,PolakN,FishlevG,Korin C,ShorerR,Parag Y,Sova M,EfratiS.Hyperbaric oxygen therapy improves neurocognitive functions and symptoms ofpost-COVID condition:randomized controlled trial.SciRep.2022 Jul12;12(1):11252.doi: 10.1038/s41598-022-15565-0. (https://pubmed.ncbi.nlm.nih.gov/35821512)

- Robbins T,GonevskiM,Clark C,Baitule S,SharmaK,MagarA,PatelK,SankarS, Kyrou I,AliA,Randeva HS.Hyperbaric oxygen therapy forthe treatmentoflong COVID:earlyevaluationofa highlypromising intervention.Clin Med (Lond).2021 Nov;21(6):e629-e632.doi:10.7861/clinmed.2021-0462. (https://pubmed.ncbi.nlm.nih.gov/34862223)

- Kjellberg A,Abdel-Halim L,HasslerA,ElGharbiS,Al-EzerjawiS,Bostrom E,Sundberg CJ,Pernow J,Medson K,KowalskiJ H,RodriguezWallberg KA,Zheng X,Catrina S, RunoldM,Stahlberg M,Bruchfeld J,Nygren-BonnierM,Lindholm P.Hyperbaric oxygenfortreatmentoflong COVID-19 syndrome (HOT-LoCO):protocolfora randomised,placebo-controlled,double-blind,phase IIclinicaltrial.BMJ Open.2022 Nov2;12(11):e061870.doi:10.1136/bmjopen-2022-061870. (https://pubmed.ncbi.nlm.nih.gov/36323462)

- Akarsu S,Tekin L,Ay H,CarliAB,Tok F,Simsek K,Kiralp MZ.Theefficacy of hyperbaric oxygen therapy in the managementofchronic fatigue syndrome. Undersea HyperbMed.2013 Mar-Apr;40(2):197-200.Erratum In:Undersea HyperbMed.2013 May-Jun;40(3):312. (https://pubmed.ncbi.nlm.nih.gov/23682549)

Study Record Dates

These dates track the progress ofstudy record and summary results submissions to ClinicalTrials.gov.Studyrecords and reported results are reviewed by the NationalLibrary of Medicine(NLM)to make sure they meetspecific quality controlstandards before being posted on the public website.

Study Registration Dates

FirstSubmitted

2023-11-01

FirstSubmitted thatMetQC Criteria

2023-11-01

FirstPosted

2023-11-07

Study Record Updates

Letztes Update übermittelt,das die QC-Kriterien erfüllthat

11.02.2025

Letztes Updateveröffentlicht(geschätzt)

12.02.2025

Zuletztüberprüft

2024-09

Weitere Informationen

Begriffe im Zusammenhang mitdieserStudie

SchlüsselwörterbereitgestelltvonCarmen Scheibenbogen,Charité,Berlin,Deutschland

Post-COVID-Syndrom
Lange COVID
Chronisches Erschöpfungssyndrom

Weitere relevante MeSH-Begriffe

Krankheit
Pathologische Prozesse
Muskelerkrankungen
Erkrankungen des Bewegungsapparates
Enzephalomyelitis
Neuroinflammatorische Erkrankungen
Erkrankungen des Nervensystems
Neuromuskuläre Erkrankungen
Chronische Krankheit
Krankheitsattribute
Erschöpfungssyndrom,chronisch

Syndrom

Plan für individuelle Teilnehmerdaten (IPD)

Planen Sie, individuelle Teilnehmerdaten (IPD) weiterzugeben?

NEIN

Arzneimittel- und Geräteinformationen, Studiendokumente und hilfreiche Links

Untersucht ein von der US-amerikanischen FDA reguliertes Arzneimittel

NEIN

Untersucht ein von der US-amerikanischen FDA reguliertes Geräteprodukt

NEIN

Produkt hergestellt in und exportiert von dort aus den USA

NEIN