Plan Overview

A Data Management Plan created using DMPonline

Title: Hyperbar oxygenbehandling vid sviktande lungfunktion från COVID-19 lunginflammation.

Creator: Anders Kjellberg

Principal Investigator: Anders Kjellberg

Data Manager: Anders Kjellberg

Affiliation: Karolinska Institutet

Funder: Swedish Research Council

Template: Swedish Research Council Template

ORCID iD: 0000-0002-4819-1024

Project abstract:

Introduction: Corona virus disease 2019 (COVID-19) may cause severe pneumonitis and trigger a massive inflammatory response that requires ventilatory support. The intensive care unit (ICU)-mortality has been reported to be as high as 62%. Dexamethasone is the only of all anti-inflammatory drugs that have been tested to date that has shown a positive effect on mortality. We aim to explore if treatment with hyperbaric oxygen (HBO) is safe and effective for patients with moderately severe COVID-19. Our hypothesis is that HBO can prevent ICU admission, morbidity and mortality by attenuating the inflammatory response. The primary objective is to evaluate if HBO reduces the number of ICU admissions compared to best practice treatment for COVID-19, main secondary objectives are to evaluate if HBO reduces the load on ICU resources, morbidity and mortality and to evaluate if HBO mitigates the inflammatory reaction in COVID-19. Methods and Analysis: A randomised, controlled, phase II, open label, multicentre trial. 200 subjects with moderately severe COVID-19 and at least two risk factors for mortality will be included. Baseline clinical data and blood samples will be collected before randomisation and repeated daily for seven days, at day 14 and 30. Subjects will be randomised with a computer-based system to HBO, maximum five times during the first seven days plus best practice treatment or only best practice treatment. The primary endpoint, ICU admission, is defined by criteria for selection for ICU. We will evaluate if HBO mitigates the inflammatory reaction in COVID-19 using molecular analyses. All parameters are recorded in an electronic case report form. An independent data safety monitoring board will review the safety parameters. Ethics and Dissemination: The trial is approved by The National Institutional Review Board in Sweden (2020-01705, 2020-06279) and the Swedish Medical Product Agency (5.1-2020-36673). Trial Registration: NCT04327505. EudraCT number: 2020-001349-37

ID: 68714

Start date: 29-04-2020

End date: 31-12-2030

Last modified: 09-10-2024

Grant number / URL: KBF 2019-00446

Copyright information:

The above plan creator(s) have agreed that others may use as much of the text of this plan as they would like in their own plans, and customise it as necessary. You do not need to credit the creator(s) as the source of the language used, but using any of the plan's text does not imply that the creator(s) endorse, or have any relationship to, your project or proposal

Hyperbar oxygenbehandling vid sviktande lungfunktion från COVID-19 lunginflammation.

General Information

Project Title

A Randomized, Controlled, Open Label, Multicentre Clinical Trial to explore Safety and Efficacy of Hyperbaric Oxygen for preventing ICU admission, Morbidity and Mortality in Adult Patients With COVID-19
Acronym: COVID-19-HBO
Short Swedish title: Hyperbar oxygenbehandling vid sviktande lungfunktion från COVID-19 lunginflammation.

Project Leader

Peter Lindholm and Kenny Rodriguez-Wallberg

Registration number at the Swedish Research Council

KBF 2019-00446

Version

Version 1

Date

2020-12-27

Description of data – reuse of existing data and/or production of new data

How will data be collected, created or reused?

Data will be prospectively collected in an electronic Case Report Form (eCRF). Blood samples (Plasma and Peripheral Blood Mononuclear Cells) will be collected and stored in a biobank.
All data collected is pseudonymised
Responsible Biobank: KI Biobank
COVID-19-HBO, Institution agreement (2020-12-03)
Biobank applications: RBC 2020-682 (2020-12-03)

What types of data will be created and/or collected, in terms of data format and amount/volume of data?

Pseudonymised patient data. Demographics, medical history including COVID-19 specific history, physical parameters, blood tests, secondary infections, viral load, radiology, concomitant medications will be recorded and saved in the eCRF. The eCRF data will be exported as comma separated values (.csv). Some study specific blood tests will be stored in a biobank for later analysis with microRNA arrays, qPCR, Affymetrix NGS and functional tests of PBMC. All biobank samples are stored in Freezer PRO, all data from subsequent analysis are stored in ELN.

Documentation and data quality

How will the material be documented and described, with associated metadata relating to structure, standards and format for descriptions of the content, collection method, etc.?

The trial is conducted according to ICH-GCP, monitored by an external CRO.

How will data quality be safeguarded and documented (for example repeated measurements, validation of data input, etc.)?

Only study officials with sufficient training and delegation by the Principal (local) Investigator at each site will have access to data entry. Data entered will be monitored by the CRO according to the Monitoring plan. Source data is pre-determined, saved and can be validated.

Storage and backup

How is storage and backup of data and metadata safeguarded during the research process?

Source data is specified in a Source data Location Agreement. Most source data are saved digitally in the medical journals except for a few exemptions (such as demography; race) when eCRF is the source data. For informed consent the printed and signed form is the source data and for exclusion criteria a signed worksheet is used as source data.

How is data security and controlled access to data safeguarded, in relation to the handling of sensitive data and personal data, for example?

All sensitive and personal data is handled according to GDPR and hospital routines for digital of storing patient data. Only the study officials have access to the psedonymisation key, that is stored in a fire safe locker. A digital backup is stored regularly on a KI server with access limited to study officials.

Legal and ethical aspects

How is data handling according to legal requirements safeguarded, e.g. in terms of handling of personal data, confidentiality and intellectual property rights?

A Clinical Trial Agreement between KI and the trial sites regulate the confidentiality and intellectual property rights. All data is handled according to ICH-GCP, GDPR, local routines and regulations. Sensitive personal data will be handled according to KI:s guidelines (https://staff.ki.se/gdpr) and data will be pseudonymized and a key will be kept separately from the data.

Responsible Biobank is KI biobank, Institution agreement (2020-12-03)

There is a multicenter agreement for Biobank with Regional Biobank Centre Stockholm-Gotland (2020-682) where all samples in Sweden will be stored until release to KI Biobank

How is correct data handling according to ethical aspects safeguarded?

All data is handled according to ICH-GCP, GDPR, local routines and regulations. An informed consent form (ICF) is signed off before any collection of data is started.

The trial is approved by Etikprövningsmyndigheten (EPM) (2020-01705)

Accessibility and long-term storage

How, when and where will research data or information about data (metadata) be made accessible? Are there any conditions, embargoes and limitations on the access to and reuse of data to be considered?

The full study protocol, statistical plan and consent form will be publicly available. Data will be available on patient level; data will be pseudonymised, the full dataset and statistical code will be available upon request. A full description of the intended use of the data must be sent to the corresponding author for review and approval. Participant consent for data sharing is conditioned and new ethics approval may be required.

In what way is long-term storage safeguarded, and by whom? How will the selection of data for long-term storage be made?

Data will be stored according to KI guidelines and according to ICH-GCP for clinical trials.

Will specific systems, software, source code or other types of services be necessary in order to understand, partake of or use/analyse data in the long term?

For understanding of RNA sequencing data for the small cohort of 20 patients additional software will be required but the code will be shared upon request.

How will the use of unique and persistent identifiers, such as a Digital Object Identifier (DOI), be safeguarded?

No DOI will be stored outside the servers unless part of open access publications in which case it will not be protected outside of the regulations of the publisher

Responsibility and resources

Who is responsible for data management and (possibly) supports the work with this while the research project is in progress? Who is responsible for data management, ongoing management and long-term storage after the research project has ended?

Data management is included in the OH costs for researchers at KI. The datamanager will dedicate labour to ensure the data fulfill FAIR principles.

What resources (costs, labour input or other) will be required for data management (including storage, back-up, provision of access and processing for long-term storage)? What resources will be needed to ensure that data fulfil the FAIR principles?

Data management is included in the OH costs for researchers at KI. The datamanager will dedicate labour to ensure the data fulfill FAIR principles.