ISRCTN81080077 https://doi.org/10.1186/ISRCTN81080077

Effect of hyperbaric oxygen on recovery from exercise-induced fatigue

Submission date	Recruitment status	[_] Prospectively registered
07/01/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/01/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/01/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Although insufficient delivery of oxygen might be a factor in physical and perceived fatigue, the relationship between exposure to hyperbaric oxygen (HBO, delivery of oxygen at a pressure greater than normal) and recovery from perceived fatigue remains unexplained. The purpose of this study was to investigate the effects of exposure to HBO after long-duration, medium-intensity training on recovery from perceived fatigue.

Who can participate?
Healthy male university students who exercised regularly, aged 20 to 30 years of age

What does the study involve?
Fatigue is induced using an exercise bike at a moderate intensity of 75% of maximum heart rate for 60 minutes. After the workout, participants randomly receive an intervention comprising exposure to HBO or an air placebo in a single-blind experimental trial. Blood tests are conducted and perceived fatigue is evaluated at five time points. One week later, participants switch to the other intervention and repeat the study.

What are the possible benefits and risks of participating?
The possible benefits will be an improvement in recovery from fatigue. The possible risks include otitis media with effusion (ear fluid buildup), perforated (burst) eardrums and pneumothorax (collapsed lung), but pneumothorax is extremely rare.

Where is the study run from?
Tokyo Medical and Dental University (Japan)

When is the study starting and how long is it expected to run for?
November 2010 to August 2014

Who is funding the study?
Tokyo Medical and Dental University (Japan)

Who is the main contact?
Kazuyoshi Yagishita, yagishita.orth@tmd.ac.jp

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Kazuyoshi Yagishita

ORCID ID
http://orcid.org/0000-0003-3809-8931

Contact details
1-5-45 Yushima, Bunkyo-ku
Tokyo
Japan
1138519
+81-3-5803-5341
yagishita.orth@tmd.ac.jp

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
12345

Study information

Scientific Title
Effect of hyperbaric oxygen after moderate-intensity exercise on fatigue: a single-blind crossover randomized trial

Study objectives
Hyperbaric oxygen will reduce fatigue after long-duration, moderate-intensity exercise.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 27/12/2011, Institutional review board of Tokyo Medical and Dental University (1-5-45 Yushima, Bunkyo-ku, Tokyo, 1138519, Japan; +81-3-5803-4547; rinri.adm@tmd.ac.jp), ref: 2000-901

Study design
Single-blind crossover randomized trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Healthy participants with fatigue after moderate-intensity exercise

Interventions
The study used a crossover design in which all subjects received both the hyperbaric oxygen (HBO) intervention and air placebo following with an interval of 1 week. The subjects were randomly assigned to either the HBO or placebo air group. In the initial trial, five subjects received HBO treatment and four received placebo. Subsequently, in the crossover trial, four subjects received HBO treatment and five received placebo.

The HBO intervention protocol consisted of 60 min of inhaling pure oxygen using a mask at pressures up to 2.5 ATA with two 5-minute breaks to breathe air, 15 min for compression and 15 min for decompression for a total of 100 min.

The intervention for air placebo consisted of 80 min of breathing air at pressures up to 1.2 ATA, with 10 min for compression and 10 min for decompression, for a total of 100 min.

Fatigue was induced using an ergometer exercise bike at a moderate intensity of 75% of their maximum heart rate for 60 min. Post-workout, subjects randomly received an intervention comprising exposure to hyperbaric oxygen (HBO) or an air placebo in a single-blind trial.

Blood tests were conducted and perceived fatigue was evaluated by using visual analog scales (VAS) at five timepoints. Blood tests and VAS scores for fatigue were measured pre-exercise, post-exercise, post-intervention, 1.5 hours post-intervention, and 24 hours post-intervention. One week later, a crossover was conducted.

Intervention Type
Other

Primary outcome measure
Whole-body fatigue and leg fatigue were measured using the visual analogue score (VAS) at pre-exercise (test 1), post-exercise (test 2), post-intervention (test 3), 1.5 h post-intervention (test 4), and 24 hours post-intervention (test 5).

Secondary outcome measures
Muscle fatigue, inflammation, and the immune system assessed using blood tests at pre-exercise (test 1), post-exercise (test 2), post-intervention (test 3), 1.5 h post-intervention (test 4), and 24 hours post-intervention (test 5).

Overall study start date
30/11/2010

Completion date
01/08/2014

Eligibility

Key inclusion criteria
Healthy male university students who exercised regularly

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
20 Years

Upper age limit
30 Years

Sex
Male

Target number of participants
9

Total final enrolment
9

Key exclusion criteria
1. Participant had difficulty relieving pressure in their ears (which precludes or makes HBO treatment difficult)
2. Claustrophobia
3. Congenital pulmonary cysts

4. Asthma
5. History of pneumothorax or heart disease
6. Experienced heart palpitations, precordial pain, or tachycardia during the previous year

Date of first enrolment
01/08/2012

Date of final enrolment
01/08/2013

Locations

Countries of recruitment
Japan

Study participating centre
Tokyo Medical and Dental University
1-5-45 Yushima, Bunkyo-ku
Tokyo
Japan
1138519

Sponsor information

Organisation
Tokyo Medical and Dental University

Sponsor details
1-5-45 Yushima, Bunkyo-ku
Japan
Japan
1138519
+81-3-5803-4547
rinri.adm@tmd.ac.jp

Sponsor type
University/education

Website
http://www.tmd.ac.jp/english/

ROR
https://ror.org/051k3eh31

Funder(s)

Funder type
University/education

Funder Name
Tokyo Medical and Dental University

Alternative Name(s)
TMDU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Japan

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed academic journal

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because this clinical trial was conducted until 2013, and because the informed consent at the time did not obtain consent from the test participants regarding the publication of the data. The datasets generated during and/or analysed during the current study will be stored in the PC of the corresponding author.

IPD sharing plan summary
Not expected to be made available