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Effect of hyperbaric oxygen on recovery from exercise-induced fatigue

Submission date 07/01/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/01/2025	**Overall study status** Completed	
Last Edited 02/12/2025	**Condition category** Other	

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?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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).

Key secondary outcome(s))

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).

Completion date
01/08/2014

Eligibility

Key inclusion criteria
Healthy male university students who exercised regularly

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
30 years

Sex
Male

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
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1138519

Sponsor information

Organisation
Tokyo Medical and Dental University

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/11/2025	02/12/2025	Yes	No