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Can breathing pure oxygen at high pressure improve exercise-induced muscle injury recovery in baseball players?

Submission date
14/03/2019

Recruitment status
No longer recruiting

Registration date
22/03/2019

Overall study status
Completed

Last Edited
11/02/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Hyperbaric oxygen therapy (HBOT) involves a person breathing pure oxygen at higher pressure than normal air pressure. Air normally contains about 21% oxygen and 78% nitrogen, so HBOT provides more oxygen to the body than is normally breathed in. It is thought that HBOT might results in muscle injuries healing more quickly, which would be an advantage to those playing sport competitively or professionally. This study aims to investigate whether HBOT improved recovery of muscle soreness and strains caused by exercise in baseball players.

Who can participate?
Professional or amateur male baseball players in training or the baseball season who have a muscle injury caused by exercise.

What does the study involve?
The participants will be randomly allocated to one of two groups. Both groups will spend 10 sessions of 100 minutes over 5 weeks in a pressurised chamber, where the pressure will be raised to above normal. One group will breathe pure oxygen while in the chamber and the other will breathe normal air. Oxygen and nitrogen are colourless gases with no smell so the participants will not be able to tell which gas they are breathing. Before the first session, after the fifth session, after the last session and 2 weeks after the last session, the participants will be asked give a blood sample and to rate their muscle pain and how much it affects their daily activities.

What are the possible benefits and risks of participating?
Those who breathe pure oxygen might experience earlier recovery of the muscle injury. There is also a small risk of side effects caused by absorbing too much oxygen.

Where is the study run from?
Kaohsiung Chang Gung Memorial Hospital, Taiwan, Republic of China

When is the study starting and how long is it expected to run for?
August 2013 to August 2016

Who is funding the study?
Chang Gung Research Fund (Taiwan)

Who is the main contact?
Miss Chen-Yu Chen

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Chang Gung Research Fund grant CMRPG8D0411

Study information

Scientific Title
Hyperbaric oxygen therapy influence of high-intensity athletes in vivo metabolic indicators

Study objectives
HBOT could facilitate the early recovery of exercise-related muscular injury and could therefore be beneficial for elite athletes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/08/2013, Institutional Review Board (IRB) of Chang Gung Medical Foundation (123 Dinghu Rd, Guishan Township, Taoyuan County, Taiwan (R.O.C.); +886 3 3196200 ext 3707/3703; merlinchi@cgmh.org.tw), ref: 102-2994B

Study design
Prospective randomized double-blind controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Exercise-related muscular injury

Interventions
41 participants were recruited between June 2014 and December 2015 and were divided into study group and control group with 20 and 21 participants. All the participants received either HBOT or placebo sessions twice in a week. The study group and the control group stayed in a hyperbaric chamber pressurized to 2.5 and 1.3 atm, and breathed pure oxygen and general air, respectively. The duration of each session was 100 mins, and 10 sessions were completed in 5 weeks for each participant.

Intervention Type
Supplement

Primary outcome measure
1. Serum creatine phosphokinase (CPK)
2. Serum glutamic-oxaloacetic transaminase (GOT)
3. Serum myoglobin
4. Blood urine nitrogen (BUN)
5. Serum lactate
Data were collected before the treatment (T1), end of 5th HBOT (T2), end of 10th HBOT (T3), and 2 weeks after the 10th HBOT (T4).

Secondary outcome measures

1. Pain intensity assessed using the Brief Pain Inventory before the treatment (T1), end of 5th HBOT (T2), end of 10th HBOT (T3), and 2 weeks after the 10th HBOT (T4)
2. Pain interference assessed using the Brief Pain Inventory before the treatment (T1), end of 5th HBOT (T2), end of 10th HBOT (T3), and 2 weeks after the 10th HBOT (T4)

Overall study start date
21/08/2013

Completion date
19/08/2016

Eligibility

Key inclusion criteria
1. Aged 20 years or older
2. Diagnosed with prolonged (more than 2 weeks) exercise-induced muscular soreness or pain with grade I muscle strain of the extremities
3. Currently under intensive and regular baseball training or regular baseball season

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
46 (5 cases loss)

Total final enrolment
41

Key exclusion criteria
1. Pneumothorax
2. Upper respiratory tract infection
3. Recently received chest or ear surgery
4. Claustrophobic

Date of first enrolment
07/07/2014

Date of final enrolment
11/09/2015

Locations

Countries of recruitment
Taiwan

Study participating centre
Kaohsiung Chang Gung Memorial Hospital
123, Ta Pei Road, Niao Sung District
Kaohsiung
Taiwan
83301

Sponsor information

Organisation
Chang Gung Memorial Hospital

Sponsor details
123 Ta Pei Road, Niao Sung District
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abc@email.com

Sponsor type
Hospital/treatment centre

Website
http://www.cgmh.org.tw

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chang Gung Medical Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Taiwan

Results and Publications

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

Intention to publish date
30/08/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/05/2019	11/02/2020	Yes	No