

Main

Note: This record shows only 22 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register: ChiCTR
Last refreshed on: 18 April 2017
Main ID: ChiCTR-IIR-16009114
Date of registration: 2016-08-29
Prospective Registration: Yes
Primary sponsor: Taishan Medical University
Public title: The effect of high concentration of hydrogen inhalation on non-alcoholic fatty liver disease in community
Scientific title: The effect of high concentration of hydrogen inhalation on non-alcoholic fatty liver disease in community
Date of first enrolment: 2016-09-01
Target sample size: treatment group:40;control group:40;
Recruitment status: Recruiting
URL: <http://www.chictr.org.cn/showproj.aspx?proj=15145>
Study type: Interventional study
Study design: Randomized parallel controlled trial
Phase: Other

Countries of recruitment

China

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Key inclusion & exclusion criteria

Inclusion criteria: 1. aged 30-70 years old;
 2. NAFLD patients meet the diagnosis criteria according to: The diagnosis and management of non-alcoholic fatty liver disease: practice guideline by the American Association for the Study of Liver Diseases, American College of Gastroenterology, and the American Gastroenterological Association);
 3. The patients agreed to participate in the study and signed the informed consent.
 Exclusion criteria: 1) fatty liver caused by a specific cause, such as tamoxifen;
 2) combined with other causes of liver disease such as viral hepatitis (such as HBsAg or anti HCV positive), liver cirrhosis, drug-induced liver injury, autoimmune diseases, metabolic liver disease, etc;
 3) Alcohol abuse, alcohol consumption >70g/week for female patient or >140g/week for male patient;
 4) Patient who is receiving insulin treatment;
 5) patients with severe disease of other system, mental disease, or senile dementia patients, epilepsy patients; hypothyroidism or Cushing's syndrome;
 6) Have received Levocarnitine treatment within 30 days; Hypersensitive to Levocarnitine and its derivatives;
 7) Patient has participated in other drug clinical trial within 30 days;
 8) use of drugs such as calcium channel blockers, high dose of synthetic estrogens, methotrexate, amiodarone steroids, chloroquine;
 9) Pregnant or lactating female, or female of childbearing potential does not use adequate contraceptive methods;
 10) other situations that researchers think the patient is not suitable for the research.

Age minimum: 30
 Age maximum: 70
 Gender: Both

Health Condition(s) or Problem(s) studied

non-alcoholic fatty liver disease

Intervention(s)

treatment group:aerosol inhalation with hydrogen and oxygen;control group:aerosol inhalation with nitrogen and oxygen;

Primary Outcome(s)

ALT level;AST level;L/S ratio;

Secondary Outcome(s)

TG;TC;BMI;abdomen circumference;Fasting blood glucose;HDL-C;LDL-c;

Secondary ID(s)

Source(s) of Monetary Support

Special fund by ascleplus meditec in Shang hai

Secondary Sponsor(s)

Ethics review

Results

Results available:
Date Posted:
Date Completed:
URL:

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