

## 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.

<b>Register:</b>	ChiCTR
<b>Last refreshed on:</b>	27 August 2018
<b>Main ID:</b>	ChiCTR-ONC-17013055
<b>Date of registration:</b>	2017-10-20
<b>Prospective Registration:</b>	Yes
<b>Primary sponsor:</b>	Huashan Hospital Affiliated to Fudan University
<b>Public title:</b>	Therapeutic Evaluation of the Hydrogen Molecule in Chronic Inflammatory Skin Diseases and Interstitial Pneumonia Related to Autoimmune Blister Diseases
<b>Scientific title:</b>	Therapeutic Evaluation of the Hydrogen Molecule in Chronic Inflammatory Skin Diseases and Interstitial Pneumonia Related to Autoimmune Blister Diseases
<b>Date of first enrolment:</b>	2017-02-01
<b>Target sample size:</b>	hydrogen-water bathing group of the chronic inflammatory diseases:120;hydrogen-water oral-take group in patients with interstitial pneumonia related to autoimmune blister diseases:10;hydrogen-gas inhalation group in patients with interstitial pneumonia r
<b>Recruitment status:</b>	Recruiting
<b>URL:</b>	<a href="http://www.chictr.org.cn/showproj.aspx?proj=22289">http://www.chictr.org.cn/showproj.aspx?proj=22289</a>
<b>Study type:</b>	Observational study
<b>Study design:</b>	Cohort study
<b>Phase:</b>	New Treatment Measure Clinical Study

## Countries of recruitment

China

## Contacts

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## Key inclusion & exclusion criteria

Inclusion criteria: The inclusion criteria of the hydrogen-water bathing group of patients with chronic inflammatory skin diseases:

- aged 20-70 years;
- Psoriasis: patients with a history of plaque psoriasis for a minimum of 12 months:
  - All the patients were diagnosed as plaque psoriasis by two or more dermatologists. And if possible, the diagnosis will be confirmed by histopathological examination;
  - All the patients suffered conventional treatment failure or failed to reduce the existing dosage of drugs beyond topical corticosteroid and calcipotriol ointments for more than 4 months;
  - Patients with the baseline Psoriasis Area Severity Index (PASI) score range from 0 to 30.
- Parapsoriasis: patients with a history of parapsoriasis for a minimum of 12 months:
  - All the patients were diagnosed as parapsoriasis by two or more dermatologists. The diagnosis will be confirmed by histopathological and immunohistochemical findings. All biopsies reported dense lymphocytic infiltrates, occasionally with lymphocyte exocytosis;
  - Patients who had received UVA or narrow-band UVB therapy for more than 6 months without evident improvements or suffered flare-ups during phototherapy.
- other chronic inflammatory skin diseases: patients who have fulfilled the criteria of certain chronic inflammatory skin disease for more than 4 months and have been resistant to the present therapy.
- Patients who fully understand of the study and can be treated and followed up regularly.

The inclusion criteria of the hydrogen-water control group of patients with chronic inflammatory skin diseases:

- aged 20-70 years;
- Psoriasis: patients with a history of plaque psoriasis for a minimum of 12 months:
  - All the patients were diagnosed as plaque psoriasis by two or more dermatologists. And if possible, the diagnosis will be confirmed by histopathological examination;
  - Patients with the baseline Psoriasis Area Severity Index (PASI) score range from 0 to 30.
- Parapsoriasis: patients with a history of parapsoriasis for a minimum of 12 months:
  - All the patients were diagnosed as parapsoriasis by two or more dermatologists. The diagnosis will be confirmed by histopathological and immunohistochemical findings. All biopsies reported dense lymphocytic infiltrates, occasionally with lymphocyte exocytosis.
  - Patients who fully understand of the study and can be treated and followed up regularly.

The inclusion criteria of the hydrogen-molecule therapy group of patients with interstitial pneumonia related to autoimmune blister diseases:

- Aged 30-85 years;
- Patients fulfill the diagnosis criteria of autoimmune blister diseases including clinical,histopathological and immunofluorescence findings;
- Patients fulfill the diagnosis criteria of interstitial pneumonia;
- The patients will be divided into two subgroups according to their own decision and objective condition:
  - hydrogen-water oral-intake group;
  - hydrogen-gas inhalation group;
- Patients who fully understand of the study and can be treated and followed up regularly.

The inclusion criteria of the control group of patients with interstitial pneumonia related to autoimmune blister diseases.

- Aged 30-85 years;
- Patients fulfill the diagnosis criteria of autoimmune blister diseases including clinical,histopathological and immunofluorescence findings;
- Patients fulfill the diagnosis criteria of interstitial pneumonia;
- Patients who fully understand of the study and can

Exclusion criteria: The exclusion criteria of the hydrogen-water bathing group of patients with chronic inflammatory skin diseases.

- Psoriasis:
  - Patients diagnosed as pustular psoriasis or erythrodermic psoriasis;
  - Patients received systemic corticosteroids within one year;
  - Patients received biological agents within one year.
- Parapsoriasis:

- 1) Patients diagnosed as mycosis fungoides;
- 2) Patients with axillary or inguinal lymphadenopathy;
- 3) Patients with splenomegaly or hepatomegaly;
- 4) Patients with serious and rapid emaciation;
3. Patients with any other chronic skin diseases for more than 3 months;
4. Patients with serious infection;
5. Patients with serious cardiovascular diseases;
6. Patients with moderate to serious anemia;
7. Patients with epilepsy or other serious mental disorders.
8. Patients with pregnancy.
9. The area of skin erosion /ulcer larger than 1% BSA.
10. Patients participate in other studies simultaneously.
11. Patients unable to receive treatment regularly.

The exclusion criteria of the control group of patients with chronic inflammatory skin diseases.

1. Psoriasis:
  - 1) Patients diagnosed as pustular psoriasis or erythrodermic psoriasis;
  - 2) Patients received systemic corticosteroids within one year;
  - 3) Patients received biological agents within one year.
2. Parapsoriasis:
  - 1) Patients diagnosed as mycosis fungoides;
  - 2) Patients with axillary or inguinal lymphadenopathy;
  - 3) Patients with splenomegaly or hepatomegaly;
  - 4) Patients with serious and rapid emaciation.
  3. Patients with any other chronic skin diseases for more than 3 months;
  4. Patients with serious infection, cardiovascular diseases and other serious systemic diseases;
  5. Patients with epilepsy or other serious mental disorders;
  6. Patients with pregnancy;
  7. Patients participate in other studies simultaneously;
  8. Patients unable to receive treatment regularly;

The exclusion criteria of the hydrogen-molecule therapy group and control group of patients with interstitial pneumonia related to autoimmune blister diseases:

1. Patients with factors which could have influence on the observation of the study, including 1) other autoimmune diseases; 2) chronic skin diseases for more than 3 months; 3) other diseases requiring long-term use of systemic corticosteroids;
2. Other primary lung diseases which could develop into interstitial pneumonia: 1) infectious lung diseases including tuberculosis, community acquired pneumonia, etc.; 2) COPD; 3) silicosis; 4) long-term administration of drugs with lung-targeted toxicity;
3. Acute phase of interstitial pneumonia;
4. Patients with cardiovascular diseases and other serious diseases;
5. Patients with epilepsy or other serious mental disorders;
6. Patients with pregnancy;
7. Patients participate in other studies simultaneously;
8. Patients unable to receive treatment regularly.

Age minimum:

Age maximum:

Gender: Both

#### Health Condition(s) or Problem(s) studied

1. Chronic Inflammatory Skin Diseases; 2. Interstitial Pneumonia Related to Autoimmune Blister Diseases

#### Intervention(s)

hydrogen-water bathing group of the chronic inflammatory diseases:hydrogen-water bathing and maintain the previous therapy;hydrogen-water oral-take group in patients with interstitial pneumonia related to autoimmune blister diseases:oral administration of hydrogen water and maintation the previous therapy;hydrogen-gas inhalation group in patients with interstitial pneumonia related to autoimmune blister diseases:inhalation of hydrogen-gas and maintain the previous therapy;the control group of the chronic inflammatory diseases:maintain the previous therapy;the control group in patients with interstitial pneumonia related to autoimmune blister diseases:maintain the previous therapy;

#### Primary Outcome(s)

Psoriasis Area Severity Index, PASI;the size of the skin eruption in patients of parapsoriasis;alveolar-arterial oxygen difference in partial pressures, P(A-a)O<sub>2</sub>;high-resolution CT of lung;composite physiologic index, CPI;

#### Secondary Outcome(s)

visual analog scale;quality of life measurement tools with respiratory questionnaires;the clinical-radiological-physiological dyspnea score;total lung capacity, TLC;diffusing capacity for carbon monoxide, Dlco;forced vital capacity, FVC;

#### Secondary ID(s)

#### Source(s) of Monetary Support

the HOPE Program launched by the Branch Association of Hydrogen Biomedicine, China-Japan Medical Science and Technology Exchanges Association

#### Secondary Sponsor(s)

#### Ethics review

Status: Approved

Approval date: 02/07/2018

Contact:

Cuiyun Wu

#### Results

**Results available:**

**Date Posted:**

**Date Completed:**

**URL:**

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