

# To explore the role of insulin-like growth factor 1 (IGF-1) in the development of thyroid associated ophthalmopathy

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<b>Registration date</b> 16/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/05/2017	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Thyroid-associated ophthalmopathy (TAO) is an autoimmune process that affects the orbital and periorbital tissue (the area around the eye), and the thyroid. It can cause eyelids to retract, proptosis (protusion or displacement of the eye), chemosis (swelling of the lines inside the eye), edma (swelling) around the eye and has social and cosmetic consequences. It does not usually cause vision loss but can threaten vision. Insulin-like growth factor 1 (IGF-1), a hormone that is similar to insulin, could play a role in TAO. Earlier studies have shown that there was no difference between IGF-1 levels in patients with severe TAO but this research only used a small sample of patients, therefore a larger study would be helpful in determining the role of IGF-1. The aim of this study is to determine the role of insulin-like growth factor 1 (IGF01) in the development of thyroid associated ophthalmopathy.

### Who can participate?

Adults aged 18 and older who have thyroid associated ophthalmopathy

### What does the study involve?

Participants provide blood samples. While they are undergoing their normally scheduled surgery, orbital samples from the surgical waste are taken. The IGF-1 in serum levels and the IGF-1 concentration in the orbital fibroblasts are analysed using the Enzyme-linked immunosorbent assay (ELISA) kit and are compared. There is no further follow up for participants.

### What are the possible benefits and risks of participating?

Participants may benefit from being notified of the results of their blood test. There no notable minimal risks of donating orbital tissues. Participants may feel discomfort when giving blood samples.

### Where is the study run from?

Peking Union Medical College Hospital (China)

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

January 2010 to January 2011

Who is funding the study?

Peking Union Medical College Hospital and State Scholarship Fund (China)

Who is the main contact?

Dr Yong Zhong

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Yong Zhong

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

To determine the correlation between clinical activity scores of patients with thyroid associated ophthalmopathy (TAO) and their locally produced and / or systemically circulated insulin-like growth factor 1 (IGF-1): a single-centre case-controlled study

### Study objectives

Earlier study showed no difference between IGF-1 serum levels of severe TAO patients, but due to the limited number of TAO patients recruited in this study, we want to repeat this study with more TAO patients involved in. In addition, we hypothesise that the IGF-1 produced locally

around orbit is independently from systemically circulated IGF-1. To accomplish this, we need the orbital tissue from TAO patients to culture the orbital fibroblast in order to investigate its secretion effect of IGF-1.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethical Committee Board of the Peking Union Medical College Hospital approved on 03/01/2010

**Study design**

Single-centre case-controlled study

**Primary study design**

Observational

**Secondary study design**

Non randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Thyroid associated ophthalmopathy

**Interventions**

The IGF-1 in serum levels and IGF-1 concentration in culture media of orbital fibroblasts were determined by an Enzyme-linked immunosorbent assay (ELISA) kit. No follow up after the sample collection.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

No correlation was found between levels of either total or free IGF-1 in serum with clinical activity score (CAS) of TAO patients, but the IGF-1 in culture medium of orbital fibroblast from TAO patients positively correlated with CAS.

**Secondary outcome measures**

The IGF-1 level in culture medium of orbital fibroblast, determined by a commercial enzyme linked immunosorbent assay ELISA kit, after 48hr in culture.

**Overall study start date**

03/01/2010

**Completion date**

03/01/2011

## Eligibility

**Key inclusion criteria**

1. TAO patients and healthy controls above 18-year old, either sex
2. Body mass index (BMI) (18.5-25 kg/m<sup>2</sup>)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Around 20 TAO patients and normal donors for blood collection, 5 TAO patients and healthy controls orbital tissue collection.

**Key exclusion criteria**

Individuals with:

1. Non-thyroid autoimmune diseases
2. Asthma
3. Granulomatous disease
4. Sinusitis
5. Human immunodeficiency virus (HIV) infection
6. Pregnancy
7. Undercurrent illness

**Date of first enrolment**

03/01/2010

**Date of final enrolment**

03/01/2011

## Locations

**Countries of recruitment**

China

**Study participating centre**

1 Shuaifuyuan

Beijing

China

100730

## **Sponsor information**

**Organisation**

Peking Union Medical College Hospital (China)

**Sponsor details**

1 Shuaifuyuan

Dongdan

Dongcheng District

Beijing

China

100730

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/04jztag35>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

China Scholarship Council (China) - State Scholarship Fund (File No. 2010621116)

**Funder Name**

Peking Union Medical College Hospital (China)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration