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

Submission date	Recruitment status	[ ] Prospectively registered
03/08/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/08/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/05/2017	Eye Diseases	[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Screening

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(s)
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.

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

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/m2)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

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
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100730

Sponsor information

Organisation
Peking Union Medical College Hospital (China)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration