

Document Cover page

Official Title of the Study

- A Study for the Ocular Toxocariasis in the Patients Who Were Diagnosed With the Pulmonary Toxocariasis, and Ocular Toxocariasis Cohort: TOXOCARA Study

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## Research Protocol

**Brief Title:** A Study for the Ocular Toxocariasis Patients with the Pulmonary Toxocariasis, and Ocular Toxocariasis Cohort

**Official Title:** A Study for the Ocular Toxocariasis in the Patients Who Were Diagnosed With the Pulmonary Toxocariasis, and Ocular Toxocariasis Cohort: TOXOCARA Study

### PRINCIPAL INVESTIGATOR:

Other investigators:

**Institution and address:** Division of Pulmonology and Critical Care Medicine, Ulsan University Hospital, University of Ulsan, Ulsan, South KOREA

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**Sponsor:** University of Ulsan

**Collaborators:** Ulsan University Hospital

### INDEX.

Condition or disease  
Toxocariasis  
Ocular Toxocariasis  
Pulmonary Toxocariasis  
Ground Glass Opacity (GGO)  
Toxocara Canis Infection (Canine Roundworms)  
Law Liver  
Law Meat  
Serum Toxocara Antibody  
Toxocara Larva Migrans

### SCOPE

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## Study Description

### Brief Summary:

TOXOCARA Study is a prospective observational cohort study. The aim of this study is to evaluate the incidence of ocular toxocariasis (OT) associated with pulmonary toxocariasis (PT) in patients who were diagnosed by chest diagnostic image tests (chest X-ray, chest CT) with migrating ground glass opacity or nodular lesions. Also a cohort study is to track the results of treatment for diagnosed ocular toxocariasis (OT) patients.

### Detailed Description:

*Toxocara canis* (also known as dog roundworm) is wide-reaching parasite of dogs and other canids. It can spread between animals such as cats, pigs and cows by ingestion of worm eggs from the feces of an infected animal.

In humans, two pathways of infection are known: first, ingestion of the eggs and second, larvae encapsulated in the tissues of the infected animal.

The encapsulated larvae hatch in the small intestine and pass through the barrier to the portal vein, the liver, the lung, the eye, etc. and remain as encapsulated larvae or survive for a period of time.

Infection into humans has been reported through ingestion of uncooked liver of cows, pigs, sheep, chickens, and meat (muscle).

When encapsulated larvae migrate to the body such as lungs, eosinophils activate and proliferate to eliminate the parasites.

They can be expressed as ground glass opacity (GGO) or nodular lesion by aggregated eosinophils, which are mistaken for lung cancer or pneumonia to be investigated.

Asthma exacerbation, cough and other symptoms of respiratory system could be revealed, but often asymptomatic.

In this study, the investigators defined pulmonary toxocariasis (PT) as a positive form of serum toxocara Ab and migrating pulmonary GGOs or nodular lesions in chest diagnostic image tests (chest X-ray, chest CT) from the patient.

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Also ocular toxocariasis (OT) is defined by the clinical manifestation of intraocular infection by *Toxocara* larvae with a positive result of serum toxocara Ab.

Clinical manifestations of OT may also cause blindness of peripheral granuloma, optic neuritis, chorioretinitis, conjunctivitis, keratitis, iridocyclitis and cataract.

The investigators want to investigate the incidence of OT associated with PT in patients with chest diagnostic image tests (chest X-ray, chest CT) with migrating GGOs or nodular lesions. Also a cohort study is to track the results of treatment for diagnosed OT patients.

## SAMPLE SIZE

Estimated Enrollment: 400 participants

Observational Model: Cohort

Time Perspective: Prospective

Target Follow-Up Duration: 3 Years

In a preliminary study, one case of ocular toxocariasis (OT) among 12 cases of pulmonary toxocariasis (PT) was diagnosed (about 8%).

Based on this, the investigators aimed at 400 pulmonary toxocariasis (PT): 32 ocular toxocariasis (OT).

### Statistical analysis

All analyses in this study will be pre-specified. Statistical analysis will be performed using SPSS 21 and Graphpad PRISM 6.0. The results will be expressed as means  $\pm$  SE. Summary data will be reported as mean  $\pm$  SEM. Statistical significance will be confirmed at a p value of  $<0.05$ .

Parametric statistical tests: Student T-test, paired t- test, One-way ANOVA, Fisher's exact test, Chi-square

Non-parametric statistical tests: Mann-Whitney U test, Wilcoxon signed rank test

: simple linear regression, multiple regression analysis

### Predictive side effects and precautions for the study

In the present study, blood tests such as CBC, eosinophil count, toxocara Ab, and ocular examinations for screening purposes will be generally performed.

The results of this study suggest that there is no additional side effect because it is a common blood test and ocular examination.

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Consideration of the safety of the subjects (test suspension, serious adverse reaction / countermeasures for adverse reactions, etc.)

Although there is no additional side effect of this study, if the adverse reaction occurs, it will be stopped immediately. The investigator will notify the patient immediately.

How to secure research ethics

All the investigators will strictly observe the Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, which defines the specific purpose, method and ethics of medical research.

All the investigators participating in this study will comply with the measures necessary for securing the ethics of this study, that is, to guarantee autonomy of patient participation, to provide sufficient explanation, to guarantee full withdrawal and to prohibit the privacy of patients.

## Study Design

Study Type: Observational (cross sectional, cohort)  
 Estimated Enrollment: 400 participants  
 Observational Model: Cohort  
 Time Perspective: Prospective  
 Target Follow-Up Duration: 3 Years

Actual Study Start Date: July 10, 2017  
 Estimated Primary Completion Date: July 31, 2020  
 Estimated Study Completion Date: July 31, 2020

## Outcome Measures

- 1) Primary Outcome Measure: Number of patients with pulmonary toxocariasis (PT) [Time Frame: at baseline]
- Patients who have a positive result of serum toxocara Ab and migrating pulmonary GGOs or nodular lesions and history of eating of law animal liver or meat or history of having the pets such as dogs and cats.

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- 2) Number of patients with ocular toxocariasis (OT) [Time Frame: at baseline]
  - Patients who have the clinical manifestation of intraocular infection by Toxocara larvae and a positive result of serum toxocara Ab and history of eating of law animal liver or meat. (and/or migrating pulmonary GGOs or nodular lesions) or history of having the pets such as dogs and cats.
  
- 3) Number of patients with ocular toxocariasis (OT) among the patients with pulmonary toxocariasis (PT), [Time Frame: at baseline]
  - Patients who have ocular toxocariasis (OT) with pulmonary toxocariasis (PT)

#### Secondary Outcome Measures:

- 1) Incidence of Cysticercosis [Time Frame: at baseline]
  - Patient who have a positive result of serum cysticercosis Ab and history of eating of law animal liver or meat. (and/or migrating pulmonary GGOs or nodular lesions)
  
- 2) Incidence of Sparganosis [Time Frame: at baseline]
  - Patient who have a positive result of serum sparganum Ab and history of eating of law animal liver or meat. (and/or migrating pulmonary GGOs or nodular lesions)
  
- 3) Incidence of Clonorchiasis [Time Frame: at baseline]
  - Patient who have a positive result of serum clonorchis sinensis Ab and history of eating of the law freshwater fish or its cuisine. (and/or migrating pulmonary GGOs or nodular lesions)
  
- 4) Incidence of Paragonimiasis [Time Frame: at baseline]
  - Patient who have a positive result of serum paragonimus westermani Ab and history of eating of the law freshwater crabs or crayfish or its cuisine. (and/or migrating pulmonary GGOs or nodular lesions)
  
- 5) Incidence of Anisakiasis [Time Frame: at baseline]

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- Patient who have a positive result of serum anisakis Ab and history of eating of the law oceanic fish or its cuisine. (and/or migrating pulmonary GGOs or nodular lesions)
- 6) Clinical course of the patients with ocular toxocariasis (OT) after treatment [Time Frame: 3 years]
- Follow-up : ocular toxocariasis cohort (clinical course of the patients with ocular toxocariasis (OT) after treatment by ophthalmologists)

### Eligibility Criteria

- 1) Eligible for Study: 18 Years and older
- 2) Sexes Eligible for Study: All
- 3) Gender Based: No
- 4) Accepts Healthy Volunteers: No
- 5) Sampling Method: Probability Sample

### Study Population

- 1) The investigators defined pulmonary toxocariasis (PT) as a positive form of serum toxocara Ab and migrating pulmonary GGOs or nodular lesions in chest diagnostic image tests (chest X-ray, chest CT) from the patient.
- 2) Ocular toxocariasis (OT) is defined by the clinical manifestation of intraocular infection by Toxocara larvae and a positive form of serum toxocara Ab.

### Criteria

#### Inclusion Criteria:

- 1) Aged 18 years and older
- 2) Patient who has positive result of Toxocara Ab
- 3) Patient who has history of eating of law animal liver or meat
- 4) Patient who has the chest diagnostic image tests (chest X-ray, chest CT) with migrating ground glass opacity or nodular lesions.

#### Exclusion Criteria:

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- 1) Age < 18 years
- 2) Pregnant woman
- 3) Malignant patient
- 4) Patient who has pulmonary infectious lesion such as pneumonia, fungus and tuberculosis
- 5) Patients who were diagnosed by benign or malignant pulmonary nodule
- 6) Patient who was not consented

### Contacts and Locations

Contacts :

Locations: South Korea

Ulsan University Hospital, 877 Bangeojin Sunwhan-doro, Ulsan, South Korea, 44033

Other Study ID Numbers: UUH 2017-06-012-001

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