

# The retro-orbital fibroblast: a key player in Graves\* ophthalmopathy and a target for therapy.

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Development, optimization and implementation of retro-orbital fibroblast cultures in our laboratory.

|                              |                         |
|------------------------------|-------------------------|
| <b>Ethical review</b>        | Approved WMO            |
| <b>Status</b>                | Recruiting              |
| <b>Health condition type</b> | Thyroid gland disorders |
| <b>Study type</b>            | Observational invasive  |

## Summary

### ID

NL-OMON35634

### Source

ToetsingOnline

### Brief title

Graves' and the retro-orbital fibroblast.

### Condition

- Thyroid gland disorders
- Ocular infections, irritations and inflammations
- Autoimmune disorders

### Synonym

Graves' disease

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Oogziekenhuis Rotterdam

**Source(s) of monetary or material Support:** Stichting Wetenschappelijk Onderzoek

## Intervention

**Keyword:** Auto-immune reaction, Cell culture, Graves' ophthalmopathy, Thyroid

## Outcome measures

### Primary outcome

Production of IL-16 by orbital fibroblast in culture after stimulation with patient IgG.

### Secondary outcome

Production of RANTES, hyaluronan and the proliferation level of orbital fibroblasts in culture after stimulation with patient IgG.

## Study description

### Background summary

In the present model of immune pathogenesis of Graves\* ophthalmopathy, a concerted action of various immune cells and antibodies is conjectured to cause this thyroid eye disease. In vitro studies may help to understand these processes more thoroughly.

### Study objective

Development, optimization and implementation of retro-orbital fibroblast cultures in our laboratory.

### Study design

Laboratory study of immunological processes involving the retro-orbital fibroblast.

### Study burden and risks

Participants of this study do not benefit from the results of this study. Risks are negligible.

## Contacts

### Public

Oogziekenhuis Rotterdam

Schiedamse Vest 180

3011 BH Rotterdam

NL

### Scientific

Oogziekenhuis Rotterdam

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

General inclusion criteria:

- age  $\geq$  18 years
- written informed consent; Graves\* patients:
- hyperthyroid
- raised free thyroxin (fT4) level
- decreased TSH level
- diffuse non-nodular appearance of thyroid on palpation, scan or ultrasonography
- positivity for TSH-receptor antibodies (Brahms Diagnostics, Berlin, Germany); Contrast AT patients:
- clinically hypothyroid
- lowered serum fT4 level
- raised TSH level

- positive for TPO antibodies
- negative for TSH-receptor antibodies (Brahms Diagnostics, Berlin, Germany); Healthy individuals:
- self-proclaimed good health
- free of any obvious medical illness for at least two weeks prior to the blood withdrawal, including acute infections and allergic reactions
- no medication (apart from anti-conceptive hormonal therapy)

## Exclusion criteria

The exclusion criteria for all subjects in the study are: any immune disorder other than thyroid autoimmunity, serious other medical illness, recent infections (last 2 weeks), fever, pregnancy/postpartum for 6 months, obvious vascular complications.

## Study design

### Design

|                     |                                 |
|---------------------|---------------------------------|
| Study type:         | Observational invasive          |
| Intervention model: | Other                           |
| Allocation:         | Non-randomized controlled trial |
| Masking:            | Open (masking not used)         |
| Control:            | Active                          |
| Primary purpose:    | Basic science                   |

### Recruitment

|                           |            |
|---------------------------|------------|
| NL                        |            |
| Recruitment status:       | Recruiting |
| Start date (anticipated): | 01-10-2007 |
| Enrollment:               | 98         |
| Type:                     | Actual     |

## Ethics review

|              |            |
|--------------|------------|
| Approved WMO |            |
| Date:        | 12-06-2007 |

|                       |   |
|-----------------------|---|
| Application type:     | First submission  |
| Review commission:    | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO<br>Date: | 16-02-2010  |
| Application type:     | Amendment   |
| Review commission:    | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID             |
|----------|----------------|
| CCMO     | NL16991.078.07 |