

## EUGOGO STUDY B

**A multicentre randomized placebo-controlled double blind clinical trial comparing selenium and pentoxifylline in patients with mild Graves Ophthalmopathy (GO)**

**The randomization has been completed**

<b>Chief Investigator</b>	Prof Wilmar Wiersinga
<b>Design</b>	Prospective, randomized placebo-controlled double blind clinical trial with three arms
<b>Aims</b>	<p><b>To investigate whether pentoxifylline or selenium in comparison with placebo given to patients with mild GO can:</b></p> <ul style="list-style-type: none"> <li>• diminish the signs of GO</li> <li>• improve the health related quality of life</li> <li>• prevent worsening of mild GO</li> </ul>
<b>Patients</b>	<b>156 patients with mild GO</b>
<b>Eligibility</b>	<ul style="list-style-type: none"> <li>• euthyroidism for at least 2 months with antithyroid drugs or following surgery, or 6 months following radiodine administration</li> <li>• at least one sign of GO for less than 18 months</li> <li>• no previous treatment for GO</li> <li>• age 18-70 years</li> </ul>
<b>Main outcome</b>	<p><b>Primary objective outcome:</b> improvement in at least one eye in one of the following outcome measures (without deterioration in any of these measures in both eyes)</p> <ul style="list-style-type: none"> <li>• improvement in lid aperture of at least 2 mm</li> <li>• improvement in any of the Class 2 (NO SPECS classification) signs at least one grade</li> <li>• improvement in proptosis by at least 2 mm using the same Hertel exophthalmometer</li> <li>• improvement in extra-ocular muscle involvement</li> </ul> <p><b>Subjective primary outcome:</b> improvement in 6 or more points on either one (or both) the GO-quality of life scales (GO-QoL)</p>
<b>Secondary outcomes</b>	<ul style="list-style-type: none"> <li>• The Gorman Diplopia Score</li> <li>• The first 7 items of the Clinical Activity Score</li> </ul>
<b>Assessment</b>	<p>At baseline, after 3 months, 6 months and 12 months:</p> <ul style="list-style-type: none"> <li>• Assessment of thyroid function and thyroid autoantibodies</li> <li>• Ophthalmologist evaluation</li> <li>• GO-QoL</li> </ul>
<b>Intervention</b>	<ul style="list-style-type: none"> <li>• Pentoxifylline in two divided doses of 600 mg daily (total dose 1200 mg)</li> <li>• Selenium selenite in two divided doses of 100 µg each (total dose 200 µg)</li> <li>• Placebo capsules administered two times daily as a capsule</li> </ul>
<b>Duration of intervention</b>	6 months
<b>Trial duration</b>	12 months
<b>Open to</b>	Eugogo centers

<b>Participating Centers</b>	Amsterdam, Pisa, Olten, Varese, Mainz, Thessaloniky
<b>Trial Co-ordinator</b>	Prof Claudio Marcocci, Azienda Ospedaliera Universitaria Pisana, Pisa (Italy)