

Observational, multicentre study to evaluate the effectiveness in routine clinical practice of Lanreotide Autogel 120 mg at extended dosing intervals (>4 weeks) for the treatment of acromegaly: SOMACROL study

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Background: Acromegaly is usually caused by a benign pituitary tumour, with increased production of growth hormone (GH) and insulin-like growth factor 1 (IGF-1). Treatment options include surgery, followed by pharmacological treatment with dopamine agonists, somatostatin analogues, GH receptor antagonists or radiotherapy. Treatment optimization is important to decrease the burden of this often-chronic disease on the patient.

Objectives: To evaluate the effectiveness in IGF-1 control of Lanreotide Autogel (LAN) 120 mg at extended dosing intervals (EDIs) (>4 weeks) in patients with acromegaly in routine clinical practice. **Methods:** Observational, retrospective study at 38 sites (36 Spanish, 2 Portuguese) (NCT02807233). Targeted enrolment was 100 adult patients diagnosed with acromegaly, receiving LAN 120 mg at EDIs for ≥ 6 months, with available data on treatment start/schedule and blood GH and IGF-1 assay immediately before study visit, and no radiation therapy in the 6 months preceding. The primary outcome was the percentage of patients with normalized IGF-1 level after at least 6 months of LAN treatment at prolonged doses. Secondary outcomes included percentages of patients with GH levels ≤ 2.5 ng/ml or ≤ 1 ng/ml, and treated with EDIs of 5, 6, 7 or 8 weeks. Treatment satisfaction, quality of life (QoL) and treatment compliance were assessed.

Results: Of 114 patients included, 109 were evaluable. Mean (\pm S.D.) age was 59.1 (± 13.2) years. 69.7% had tumour resection performed on average 12.8 (± 9.4) years ago. 25.7% received radiotherapy on average 17.9 (± 9.4) years ago. 83.5% had comorbidities, with hypertension the most common (64.4%). 77.1% had concomitant medication for conditions besides acromegaly. LAN had been the first-line pharmacological treatment for 67.0% of the patients. 91.7% had normalized IGF-1 values. 80.6% had GH levels ≤ 2.5 ng/ml, and 58.3% had levels ≤ 1 ng/ml. The EDIs most commonly used in routine clinical practice were 8 weeks (35.8%) and 6 weeks (37.6%). AcroQoL questionnaire showed that patients had a medium level of physical [59.7 (± 24.5)] and psychological [64.9 (± 20.1)] QoL. TQ10M-9 questionnaire revealed that patients were satisfied with treatment [75.1 (± 16.6)], and considered it effective [70.6 (± 18.7)] and convenient [69.1 (± 17.6)]. General therapeutic compliance during preceding 6 months was 94.5%.

Conclusions: LAN 120 mg at EDIs (>4 weeks) during at least 6 months provided IGF-1 control in more than 90% of patients with acromegaly, with good levels of treatment satisfaction and compliance.

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