

**118648****Post authorization safety study on pitolisant (PASS-pitolisant) in narcolepsy: Response to treatment from the Italian multicenter cohort**

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**Background and aims**

14 Italian Centers enrolled 191 narcoleptic patients in the observational PASS-pitolisant. Besides drug's safety, the study analyzed variations of narcolepsy symptoms, depression, quality of life and disease burden.

**Methods**

From PASS-Pitolisant's 3<sup>rd</sup> Interim report we extracted detailed clinical data on patients who concluded the 1-year follow-up (FU) visit. Clinical Global Impression (CGI) for Excessive Daytime Sleepiness (EDS) and cataplexy severity were judged by sleep experts. Validated questionnaires were administered to evaluate EDS (Epworth Sleepiness Scale, ESS), depression (Beck Depression Inventory, BDI), quality of life (EQ-5D-5L) and disease burden (Functional Outcome of sleep questionnaire, FOSQ10).

**Results**

Of the 191 patients (76.4% narcolepsy type I and 23.6% narcolepsy type II) enrolled, 96 completed the 1-year FU visit. ESS decreased from  $15.2 \pm 4.4$  at baseline to  $12.4 \pm 4.5$  and responders (ESS  $\leq 10$  or ESS decrease  $\geq 3$ ) were 57.3%. Other main narcoleptic symptoms including cataplexy, sleep attacks, sleep paralysis and hypnagogic hallucinations ameliorated in 39.7%, 49.4%, 15.6% and 21.5% of patients, respectively. According to CGI, 87.5% of patients had improvement of EDS and 64.5% of cataplexy. Moreover, at FU visit an increase of EQ-5D-5L score (baseline: 64.7; FU: 73.6%), an increase of FOSQ-10 score (baseline:  $13.7 \pm 3.8$ ; FU:  $15.6 \pm 3.4$ ), and no worsening of BDI score for 96.3% of patients were observed.

**Conclusions**

According to PASS-Pitolisant interim report, patients recruited from the Italian centers reported improvement of narcolepsy symptoms at 1-year FU. Treatment favorably impacted on quality of life and on depressive symptoms, mitigating the burden of disease.

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**118649****Sleep disorders in patients with chronic kidney disease**

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**Background and aims**

To investigate sleep disorders in patients with Chronic kidney disease.

**Methods**

Neurological Examination and the Pittsburgh Sleep Quality Assessment Scale.

**Results**

The study involved 42 patients undergoing routine hemodialysis (15 women (35.7%), 27 men (64.2%)) the average age was  $41.6 \pm 2.8$  years. 35 patients after kidney transplantation (15 women (43%), 20 men (57%)), the average age was  $40.6 \pm 2.3$  years. For control, 40 completely healthy people, the average age of which was  $37.6 \pm 3.2$  years. In the group of patients undergoing routine hemodialysis, the main complaints were: insomnia (36%), daytime sleepiness (19%), restless legs syndrome (23.8%), frequent awakenings (21.4%). In the group of patients after the transplant, complaints of difficulty in falling asleep prevailed 45.7%; 17.1 % of patients complained of insomnia, and 37.1 % had no problems with sleep. In the control group, only 25% of patients had problems with sleep, and this was manifested in difficulty in falling asleep. The Pittsburgh Sleep Quality Assessment Scale shows the total value for all components of the PSQI scale in the group receiving hemodialysis was  $8.90 \pm 1.32$  points, in the group of patients after transplantation  $5.34 \pm 1.54$ ; in the control group –  $3.06 \pm 0.98$  points.

**Conclusions**

According to the Pittsburgh Scale, sleep problems are less common in transplanted patients than in patients receiving routine hemodialysis. The transplanted patients had significantly better overall sleep quality than the patients on maintenance hemodialysis, but at the same time, their sleep was worse than that of the healthy control group.

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**118650****Impact on the sleep of patients with COVID 19 in self-isolation: A systematic review**

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**Background and aims**

COVID-19 challenges medicine in numerous aspects, including the triggering and / or worsening of sleep disorders, which can both hinder the treatment of this disease and may imply the emergence of other morbidities, especially mental and cardiovascular diseases. For this reason, this systematic review was carried out with the objective of verifying the sleep behavior in self-isolated individuals as well as identifying which preventive and therapeutic measures can be used to decrease sleep disturbances.