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15454

Kalinix® in the daytime treatment of obstructive sleep apnoea (OSA).

Obstructive sleep apnoea, Diagnostic, Other therapies and interventions

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Introduction. Many OSA patients who do not adapt to traditional CPAP treatment. KaLinix is a smart, portable, non-invasive medical device as an alternative to OSA treatment. The daytime treatment mode delivers an external therapeutic electric wave to the patient's upper airway (UA) in short sessions.

Aims and objectives. Evaluate the efficacy of a non-invasive intelligent medical device (Kalinix), in the treatment of patients with moderate or severe OSA.

Methods. Stimulation waves are applied to tone the UA musculature and thereby reduce sleep apneas and hypopnoea events. The "day treatment" sessions consisted of six weeks of treatment, twice a week, 20 minutes long. Airway studies with 5D ultrasound and elastography were performed before and after the treatment sessions, as well as respiratory polygraphic recording.

Results. n=17; 94% of the patients improved the AHI and the obstructive desaturation index by 33%; 65% improve CT90 by an average of 41%; 82% improve the apnea index and 76% the hypopnea index. In 80% of cases there was a elastographic improvement of the UA, with similar results to the healthy population. 65% of patients improved on the Epworth test by 52%. All patients tolerated the treatment without discomfort or adverse effects, and report sleeping better, reducing snoring and feeling more rested after treatment.

Conclusions. The KaLinix day device improves apnoea and desaturation without the use of any overnight device. It would be indicated for all patients, especially those who do not adapt to traditional OSA treatments of choice such as CPAP, those who discontinue their use or as a booster therapy for other treatments.

Project promoter: Torytrans S.L.

Kalinix® in the daytime treatment of Obstructive Sleep Apnoea (OSA)

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- Kalinix® is a smart, portable, non-invasive medical device that emerges as an alternative to conventional OSA treatment in those patients that do not tolerate CPAP.
- > The daytime treatment mode delivers an external therapeutic electric wave to the patient's upper airway (UA) muscles in 20 minutes sessions.
- Aim: evaluate the efficacy of a non-invasive intelligent medical device (Kalinix ®) for the treatment of patients with moderate to severe

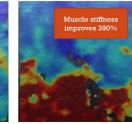


Methods

- We selected seventeen patients with a previous diagnosis of OSA and poor tolerance
- > Daytime treatment consisted in performing an electric stimulation of the UA muscles during six weeks, two sessions a week of twenty minutes.
- > We evaluated the efficacy of daytime treatment with Kalinix® by performing 5D ultrasound and elastography of the upper airway before each session and after six weeks of treatment. We compared as well with a respiratory poligraphy.

Refore treatment

After six weeks of treatment

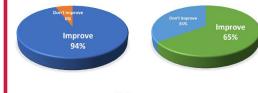


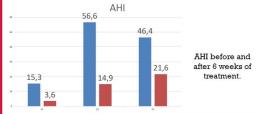
Using specific software, a quantitative analysis is performed that relates color to muscle stiffness in kilopascals (kPa).

Results

- 94% of the 17 patients improved AHI and ODI by 33%; 65% improved CT90 by an average of 41%; 82% improved the apnea index and 76% the hypopnea index.
- There was an elastography improvement in 80% of
- 65% of the patients had an improvement of 52% in the Epworth Test.
- All patients tolerated the treatment without discomfort or adverse effects.
- All patients reported a better sleep, lees snoring and feeling more rested after six weeks of treatment.

PATIENTS THAT IMPROVE THE AHI AN PATIENTS THAT IMPROVE THE CT90 AN **AVERAGE OF 33%** AVERAGE OF 41%





Conclusions

- Kalininx® as a daytime treatment device improves AHI, ODI, muscle stiffness and Epworth test without any overnight device.
- It could be indicated in those patients with poor tolerance to CPAP or as a booster therapy for other treatments.

Project promoter: Torytrans S.L.



