Clinical trial Nº EudraCT 2016-001011-21

The study for which the report is presented has the following title:

Prospective, open-label, 12-week treatment study to determine the effect of tadalafil 5 mg on clitoral blood flow in menopausal and hypertensive women with sexual interest and arousal disorder.

Authorized by the AEMPS dated 04/09/2016.

The clinical trial in question aimed to find out if 5 mg of tadalafil daily would have a beneficial effect in the treatment of sexual interest and arousal disorder in hypertensive and menopausal women.

Specifically, the objectives were as follows:

Primary objective

- To determine the effect of tadalafil on clitoral blood flow in menopausal and hypertensive women with disorder of interest and sexual arousal by Eco-Doppler.

Secondary objectives

- To evaluate the efficacy of tadalafil in the treatment of sexual interest and arousal disorder in menopausal women with hypertension, using the FSFI index (Female Sexual Function Index).

- To evaluate the efficacy of tadalafil in menopausal women with hypertension diagnosed with disorder of interest and sexual arousal using the Scale of Evaluation of Sexual Activity in Women (EVAS-M).
- To determine the effect of tadalafil on quality of life after 12 weeks of treatment according to the SF-36 Health Questionnaire.
- To evaluate the safety of tadalafil.

Reasons why the study was terminated early – Justification

According to Section 11.3 "Early study interruption at study centre" (page 54) study protocol (V02.00 / 20.MAY.2016) the sponsor can interrupt the study if the researcher is unable to include an adequate number of patients in a given period. The study started in January 2017 (First Visit / First Patient: JAN 27, 2017) and the estimated time for the recruitment of the 30 patients in the study was six (6) months, which meant around 5 patients per month. From January 2017 to February 2019, only 21 patients have been recruited and two of them could not enter the study because they did not meet the inclusion / exclusion criteria. After contacting the Principal Investigator of the study to try to speed up recruitment, the Principal Investigator explained the difficulty in obtaining the necessary number of patients due to the characteristics of the study population (menopausal and hypertensive women with sexual interest and arousal disorder) so the Promoter decided to end the study.

Conclusions

Regarding the objectives of the study, from the point of view of the expected efficacy of the product, due to the low number of recruits, it was not possible to draw conclusions in any of the sections of the objectives, both in the primary and in the secondary ones, statistically significant.

However, from a study safety point of view, it can be concluded that there were no significant adverse events (AE) related to the investigational drug. For this purpose, a summary of AE is attached, confirming that there are no adverse situations that are clinically worthy of being mentioned and that a total of forty-nine (49) AE were collected.

Summary of Adverse Events (AE) (I/III)

- All patients had at least one (1) AE
- In total 49 AE were collected

Summary:

- Serious AE: 0
- Frequency:
  - Unicque (per patient): 36
  - Repeated (in the patient): 13
  - Permanent: 0
- Intensity:
  - Low: 43
  - Moderate: 4
  - Severe: 2
- Causal relationship with the study drug:
  - Probable: 22
  - Possible: 6
  - Improbable: 8
  - Not related: 13
- Actions carried out:
  - None: 7
  - Study medication dose reduction: 0
  - Withdrawn from study medication: 2
  - Concomitant medication change: 40
- Results:
  - **Recovery : 49**