Premature termination of a Clinical Trial

Full title of the clinical Trial: Safety and efficacy of vardenafil in patients with liver cirrhosis. A randomized controlled trial.

EudraCT Number: 2010-023420-25

Sponsor: Medical University of Vienna
Represented by (name): Prof. Arnulf Ferlitsch

Reason for premature termination of the clinical trial:

50% Inclusion interim analysis did not show significant results, There is no indication for vardenafil in the treatment of portal hypertension, benefit of trial: no additional risk was noted for patients with portal hypertension taking vardenafil-.

Study results (if available):

Effect of vardenafil on portal hemodynamics in patients with mild and moderate liver dysfunction: a randomized, placebocontrolled trial

Journal of hepatology, 2018, 68, S717- Paternostro R, Heinisch B, Schwarzer R, Reiberger T, Wewalka M, Schwabl P, Ferlitsch M, Mandorfer M, Peck-Radosavljevic M, Trauner M, Ferlitsch A

Background: Erectile Dysfunction (ED) is a frequent complication in patients with cirrhosis. Phosphodiesterase type 5 inhibitors (PDE5i) are effective to treat ED. Experimental studies have suggested beneficial effects of PDE5i on portal hypertension (PHT). We assessed the effects of 7 days treatment with vardenfil (10mg o.d.; Bayer, Germany) or placebo on hepatic venous pressure gradient (HVPG) and safety in patients with cirrhosis and PHT.

Methods: 20 male cirrhotic patients with Child Pugh Score A and B were included. HVPG was assessed at baseline. After 7days of treatment HVPG response (2h after last vardenafil dose) was recorded.

Results: 20 patients were included. 3 patients on vardenafil did not finish the HVPG study (n=1 discontinuation due to headache, n=2 failure to obtain second HVPG). Thus, n=9 patients on vardenafil (Child A:4, B:5) and n=8 on Placebo (Child A:4, B:4) were analyzed per protocol. Baseline HVPG (vardenafil: 18.1±5.5; placebo: 18.3±4.5; p=0.952) was similar between groups. After 7 days of treatment HVPG was 17.8±5 mmHg in the vardenafil group and 17.4±3.9 mmHg in the placebo group; showing no significant decrease in HVPG in the vardenafil group (p=0.724) and no statistical difference in on-treatment HVPG between groups (p=0.858). Safety: 1 patient reported tinnitus and 1 patient reported fatigue and diffuse pain (foot, eyes) both on V. Those side-effects were considered non study drug related.

Conclusion: Within this randomized pilot study Vardenafil was tolerated well in most patients with Child-Pugh A/B cirrhosis. However, 7 days of Vardenafil treatment did not decrease HVPG. These results do not support previous reports on portal pressure reduction with other PDE5i.

Date and Signature of Sponsor representative:

Vienna, February 16th 2021

Dr. Arnulf Ferlitsch