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STUDY OF ANTIHYPERTENSIVE ACTIVITY OF COMBINED CAPSULES "NAVESTO"

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ABSTRACT

Research was conducted to study the specific activity of "Navesto" capsules, a combination formulation containing sacubitril and valsartan as active ingredients. The results of the research showed that, according to the toxicity classification of substances, this preparation is classified as low-toxic. It was ascertained that "Navesto" (100 mg and 200 mg capsules), developed at the Tashkent Pharmaceutical Institute (Uzbekistan), is biologically equivalent in terms of specific pharmacological action to its analogous drug, "Uperio™" (100 mg and 200 mg film-coated tablets), manufactured by Novartis Pharma S.p.A. (Italy).

Introduction:

Arterial hypertension is a leading cause of death worldwide. A 33% reduction in the prevalence of this disease between 2010 and 2030 is included in the list of global targets for combating noncommunicable diseases [1,9].

Blood pressure characterizes the force with which blood presses on the vessel walls and depends on cardiac output, circulating blood volume, and vascular elasticity, including vascular tone. The upper limit of pressure (systolic) is determined by the force of blood ejection from the heart, while the lower limit (diastolic) reflects vascular resistance during relaxation.

It should be noted that arterial hypertension is a complex condition encompassing a group of pathologies with a common symptom: persistently elevated blood pressure. The risk of developing it increases with age, in people who are overweight, and in those with a hereditary predisposition [1,2,8].

According to the latest data, hypertension affects approximately 1.28 billion adults aged 30-79 years worldwide, with approximately two-thirds of these patients living in low- and middle-income countries. Statistics also indicate that approximately 46% of adults with hypertension are unaware of their condition.

However, less than half of patients (42%) are diagnosed and receive appropriate treatment. Blood pressure control is achieved in only approximately one in five patients, representing approximately 21% of adults with hypertension [1,3,8].

Considering the relevance of the problem of arterial hypertension, the

Tashkent Pharmaceutical Institute is conducting research aimed at developing combination medications. Specifically, capsules in 100 mg and 200 mg doses containing sacubitril and valsartan as active ingredients are being developed.

The objective of this research was to investigate the specific pharmacological activity of “Navesto” capsules in dosages of 100 and 200 mg and to evaluate their biological action.

Materials and methods. The antihypertensive effect of the preparation "Navesto" (capsules 100 mg), developed at the Tashkent Pharmaceutical Institute (Uzbekistan), and the analog one "Yuperio™" (film-coated tablets, 100 mg) produced by Novartis Pharma SpA (Italy) was studied for their ability to reduce blood pressure in normotensive rabbits [4,5].

The experiment involved six rabbits weighing 1900-2200 g, divided into two groups of three animals each. The animals were anesthetized with urethane, after which the cervical spine was dissected, and the carotid artery was isolated. To record blood pressure, a stylet needle was inserted into the carotid artery and connected to a kymograph via a mercury manometer. To study the hypotensive effect, the compared preparations were administered orally to the rabbits as aqueous solutions through a pre-inserted gastric tube at a dose of 100 mg/kg. Blood pressure was measured before and 3 hours after drug administration.

The antihypertensive effect of “Navesto” (200 mg capsules), developed at the Tashkent Pharmaceutical Institute (Uzbekistan), and its analog, “Uperio™” (200 mg film-coated tablets) manufactured by Novartis Pharma S.p.A. (Italy), was studied for their ability to lower blood pressure in normotensive rabbits [6].

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To study the hypotensive effect, the compared preparations were administered to rabbits orally as aqueous solutions through a pre-inserted gastric tube at doses of 100 mg/kg and 200 mg/kg. Blood pressure was measured before and 3 hours after administration.

Statistical processing of the obtained results was carried out using the variation statistics method using the Student’s t-test in the STATISTICA program [7].

Results obtained. When studying the antihypertensive activity of the compared preparations, a kymogram recorded a decrease in blood pressure in normotensive rabbits.

Preparations in a dose of 100 mg:

In animals receiving the preparation "Navesto" (100 mg capsules), developed at the Tashkent Pharmaceutical Institute (Uzbekistan), blood pressure decreased to 102 ± 2.8 mm Hg, while the initial level was 128 ± 2.8 mm Hg.

In animals treated with the preparation "Yuperio™" (film-coated

tablets, 100 mg) manufactured by Novartis Pharma S.p.A. (Italy), a decrease in blood pressure to 98 ± 2.8 mm Hg was observed, with an initial level of 123.3 ± 2.8 mm Hg (Table 1).

Table №1

Antihypertensive efficacy of "Navesto" capsules (100 mg, Tashkent Pharmaceutical Institute, Uzbekistan) compared with Uperio™ tablets (100 mg, film-coated, Novartis Pharma SpA, Italy).

Preparation	Weight, g	Blood pressure in norm, mmHg	Blood pressure after medications (after 3 hours),mm Hg	Difference, mm Hg	Hypotensive effect, %
"Navesto" capsules	2100	130	100	30	20.3
	2300	125	100	25	
	2200	130	105	25	
	2200±100	128±2.8	102±2.8	26.6±2.8	
"Uperio™" manufactured by Novartis Pharma SpA, Italy	2200	120	95	25	20.5
	2310	125	100	25	
	2200	125	100	25	
	2233±58	123.3±2.8	98±2.8	25±0	

Preparations in a dose of 200 mg:

In animals receiving "Navesto" (200 mg capsules), blood pressure decreased to 98 ± 2.8 mm Hg, while before administration of the preparation, the blood pressure level was 125 ± 5 mm Hg. In animals receiving "Uperio™" (200 mg tablets), a decrease in blood pressure to 96 ± 3.0 mm Hg was observed, with an initial level of 124 ± 4.5 mm Hg.

A comparative analysis of the obtained data indicates that the preparations "Navesto" and "Uperio™" have comparable and statistically significant antihypertensive effects at both dosages.

Table №2

Antihypertensive efficacy of "Navesto capsules" (200 mg, Tashkent Pharmaceutical Institute, Uzbekistan) compared with "Uperio™" tablets (200 mg, film-coated, Novartis Pharma SpA, Italy).

Preparation	Weight, g	Blood pressure in norm, mmHg	Blood pressure after medications (after 3 hours), mm Hg	Difference, mm Hg	Hypotensive effect, %
"Navesto" capsules	2200	125	100	25	21.6
	2450	120	95	25	
	2400	130	100	30	
	2350±132	125±5	98±2.8	26.6±2.8	
"Uperio™" manufactured by Novartis Pharma SpA, Italy	2350	130	100	30	22.8
	2400	125	100	25	
	2100	125	95	30	
	2283±161	127±2.8	98±2.8	28.3±2.8	

In animals receiving the preparation "Yuperio™" (film-coated tablets, 200 mg) manufactured by Novartis Pharma S.p.A. (Italy), blood pressure decreased to 98 ± 2.8 mm Hg, whereas before the administration of the preparation the blood pressure level was 127 ± 2.8 mm Hg (Table 2).

Analysis of the obtained data shows that the compared preparations have comparable and statistically significant antihypertensive effects.

Conclusions: Analysis of the obtained results showed that "Navesto" capsules (100 and 200 mg), developed at the Tashkent Pharmaceutical Institute, possess a statistically significant antihypertensive effect and are biologically equivalent in specific effect to the similar preparation "Uperio™" (50, 100, and 200 mg tablets, Novartis Pharma SpA, Italy). These observations confirm the possibility of using "Navesto" as an effective alternative to the original preparation for blood pressure control.

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