

Report
For
Conducted

Monocenter clinical analytical trial to evaluate the efficacy and safety of
Baykavir in patients with influenza and / or acute viral infection

PROTOCOL ASSIGNMENT

Title	A monocentric clinical trial to evaluate the efficacy of Baykavir in patients with influenza and / or acute viral infection.
Main goal	1.Evaluation of the effectiveness of the use of a food supplement " Baykavir . 2. Product safety.
Additional goals	1. Objective and subjective sensations when using the supplement 2. Follow-up of patients, reporting of a period after which a result is established. 3. Follow-up of patients for complications / development of bacterial infection /
Study design	The current study will be open-label - all patients will receive the same doses. 1. The daily dose for adults during the first five days will be: 3x2 capsules on an empty stomach or 30 minutes before meals. 2. The daily dose for the next seven days will be (according to the researcher): 2 capsules a day on an empty stomach or 30 minutes before meals.

THE RESEARCH

The study is aimed at 35 adults / 18-85 years / patients with acute viral infection / AI /, including influenza. During the laboratory tests / Inf.A + Inf.B / no influenza disease was detected. Some patients underwent tests for coronary heart disease virus "Kovid-19", and others after the end of the disease to detect antibodies, which showed a positive result.

The current study did not aim to monitor and treat patients with Covid-19, and patients with this infection were included in the total number of patients with OVI.

The conclusions from the course of the disease of patients with OVI according to the indicators described in the protocol follow.

CONCLUSIONS

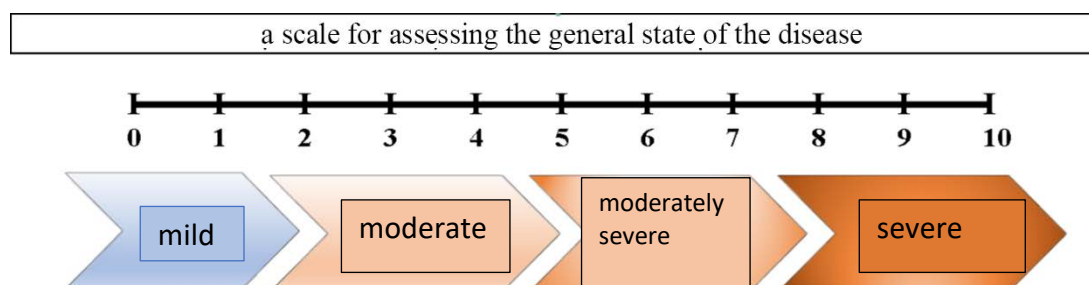
- I. All 35 patients who received Baykavir passed the viral infection without complications and did not require hospital treatment.

Note:

Only one patient was admitted to hospital at the insistence of the general practitioner / two days after his inclusion in the study /

- II. Conclusions for the subjective assessment of patients for the course of the disease / on a visual scale /:

Scale for assessing the general state of the disease (0=lightest)



1. Of all patients at the beginning of the disease / First visit / 29 consider themselves to be seriously ill and 6 to be slightly ill.

	Summary assessment of the general course of the disease Visit 1			
	0 to 1	2 to 4	5 to 7	8 to 10
	mild	moderate	moderately severe	severe
patient assessment	0	6	22	7
doctor's assessment	0	13	21	1

2. At the second visit / day 6/24 patients accepted that they were not cured and their condition was moderate.

	Summary assessment of the general course of the disease Visit 2			
	0 to 1	2 to 4	5 to 7	8 to 10
	mild	moderate	moderately severe	severe
patient assessment	2	8	19	5
doctor's assessment	3	18	9	4

3. After the third visit / 11 days / 9 patients think that they are fine, and 21 patients that subjectively they have not been cured yet

	Summary assessment of the general course of the disease Visit 3			
	0 to 1	2 to 4	5 to 7	8 to 10
	mild	moderate	moderately severe	severe
patient assessment	9	21	2	2
doctor's assessment	12	20	2	0

4. At the last visit / 24 days / 26 patients are well without complaint, 6 have the feeling that they are not completely healthy and only two still feel sick. / have a runny nose, mild muscle pain and variable headache /.

	Summary assessment of the general course of the disease Visit 4			
	0 to 1	2 to 4	5 to 7	8 to 10
	mild	moderate	moderately severe	severe
patient assessment	26	6	2	0
doctor's assessment	29	3	2	0

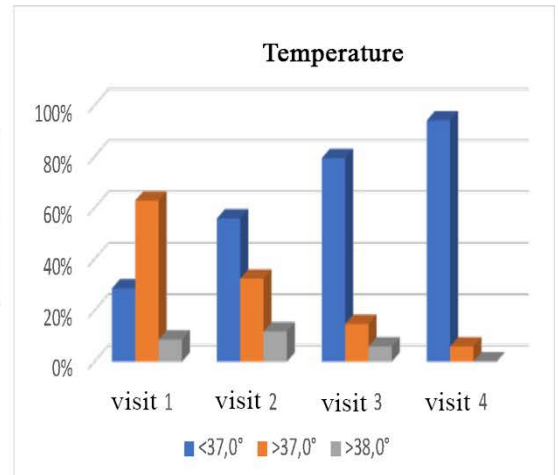
EVALUATION OF THE DOCTOR

The evaluation of the doctor who performed the examination:

The subjective assessment described by the patients at the first visits at the beginning of the disease was higher by 2 points due to the fear of coronavirus infection / Kovid-19 /.

III. Observed indicator TEMPERATURE at each visit

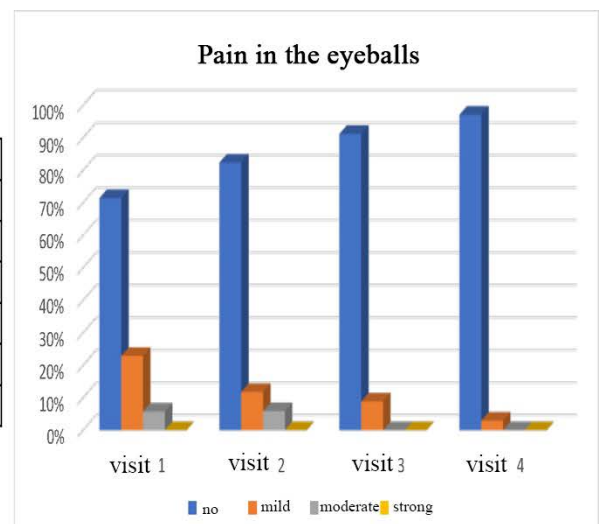
		Temperature of 35 patients per visit							
		visit 1		visit 2		visit 3		visit 4	
<37,0°	10	29%	19	56%	27	79%	32	94%	
>37,0°	22	63%	11	32%	5	15%	2	6%	
>38,0°	3	9%	4	12%	2	6%	0	0%	



1. Of the observed patients in terms of TEMPERATURE, 10 were with normal at inclusion, and 25 with elevated, and only 3 of them with more than 38 degrees.
2. Second visit / day 6 / from the beginning of the disease 19 patients had a normal temperature, 11 patients with a subfebrile and 4 patients with an elevated one.
3. Third visit / day 11 / only two patients remained with fever and had to include antibiotics and corticosteroids - Dexamethasone and Methylprednisolone.
4. Fourth visit / 24 days / only two patients have a temperature of 37 degrees.

IV. Observed symptom PAIN IN THE EYES

		Pain in the eyeballs of 35 patients per visit							
		visit 1		visit 2		visit 3		visit 4	
no	25	71%	28	82%	31	91%	33	97%	
mild	8	23%	4	12%	3	9%	1	3%	
moderate	2	6%	2	6%	0	0%	0	0%	
strong	0	0%	0	0%	0	0%	0	0%	

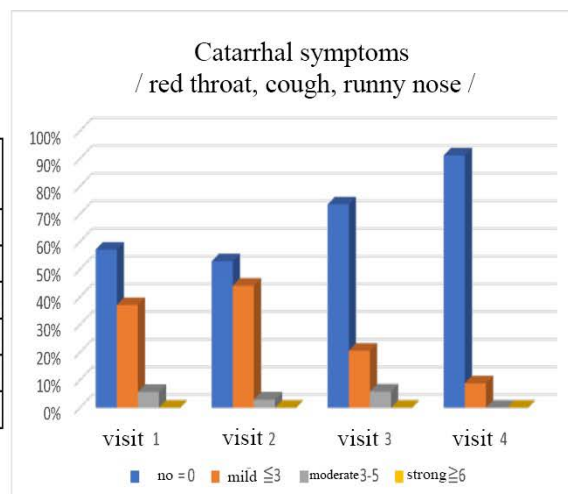


This symptom is less common.

- Only 10 patients had pain in the eyeballs at the first visit, at the second / 6th day / 6 patients, and after the 11th day only 3 felt weak ones.

V. Observed symptom CATARRHAL SYMPTOMS at each visit / sore throat, cough, runny nose /

Catarrhal symptoms / red throat, cough, runny nose / of 35 patients per visit								
	visit 1		visit 2		visit 3		visit 4	
no = 0	20	57%	18	53%	25	74%	31	91%
mild ≤ 3	13	37%	15	44%	7	21%	3	9%
moderate 3-5	2	6%	1	3%	2	6%	0	0%
strong ≥ 6	0	0%	0	0%	0	0%	0	0%



From the objective status in all patients no complication was found / bronchopneumonic focus /.

At the first visit, 20 patients showed no Catarrhal symptoms, 13 were mild and 2 were mild to moderate.

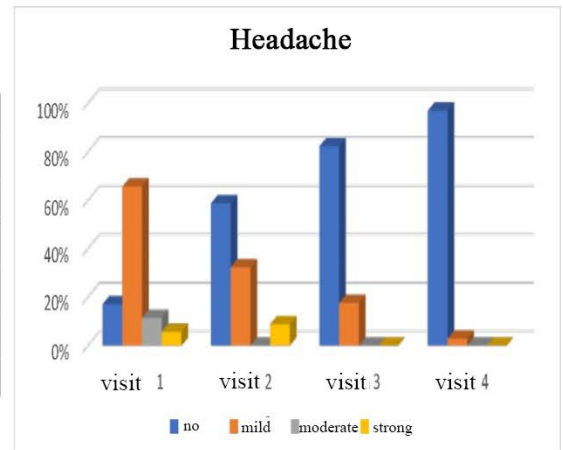
After a second visit (day 6), two of the patients, who did not have catarrhal symptoms at the beginning, appeared weak. In the remaining 18 patients, the absence of these symptoms after day 6 was confirmed. In the remaining 15 patients, catarrhal symptoms continued to persist.

After the visit 3/11 day / Only 9 patients had mild catarrhal symptoms.

After the visit 4/24 day / 3 patients remained with general malaise and mild runny nose.

VI. The symptom of a HEADACHE is observed at each visit.

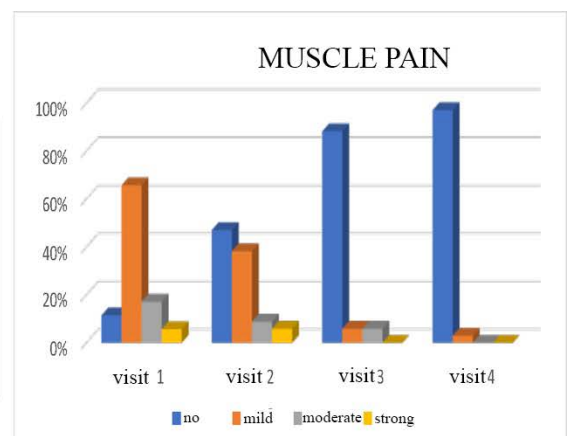
		Headache							
		of 35 patients per visit							
		visit 1		visit 2		visit 3		visit 4	
no		6	17%	20	59%	28	82%	33	97%
mild		23	66%	11	32%	6	18%	1	3%
moderate		4	11%	0	0%	0	0%	0	0%
strong		2	6%	3	9%	0	0%	0	0%



1. At the first visit / 1 day / 23 patients had a mild headache and 6 patients with a pronounced.
2. After the second visit / 6 days / 20 patients were without headache, 11 patients with mild and 3 with severe headache.
3. Third visit / day 11/28 patients were without headache and 6 with mild headache.
4. At the fourth visit / 24 days / 97% are without headache and only one with weak.

VII. There is a symptom of MUSCLE PAIN

		MUSCLE PAIN							
		of 35 patients per visit							
		visit 1		visit 2		visit 3		visit 4	
no		4	11%	16	47%	30	88%	33	97%
mild		23	66%	13	38%	2	6%	1	3%
moderate		6	17%	3	9%	2	6%	0	0%
strong		2	6%	2	6%	0	0%	0	0%



1. At the beginning of the first day, 4 patients were without pain, 23 patients with mild and 8 with severe.
2. At the visit 2/6 day / without pain were 16 patients, mild 13 patients and 5 with severe pain.

3. At the visit, three / 11 days / 30 patients were without pain, two with mild and two with moderate.
4. At the 4/24 day visit / 97% or 33 patients had no complaints and only 1 was mild.

EFFICIENCY

Evaluation of the effectiveness of Baykavir in 35 patients / 100% / based on average visits:

- At the second visit (day 6) of inclusion, 58% of patients were diagnosed as clinically healthy.
- On the third visit / 11 days / from the inclusion the percentage of cured patients reached 82%.

Note:

After the 24th day, 3 patients (9%) remained with mild catarrhal symptoms (runny nose, mild cough and subfibrillary fever -37 degrees), 91% of patients were cured.

Important!

When conducting the clinical trial, the different age groups and age changes are not taken into account / accompanying diseases without excluding criteria /.

PATIENT SAFETY

At the end of the clinical trial, all 35 patients tolerated Baykavir very well without complaints.

Note:

A patient with chronic gastritis developed symptoms of exacerbation (epigastric pain, nausea, vomiting).