Report
For
Conducted
Monocenter clinical analytical trial to evaluate the efficacy and safety of a food supplement "**FIBROLEX** "in patients with residual symptoms after getting sick Crown viral infection Kovid-19

PROTOCOL ASSIGNMENT

Title	Monocenter clinical analytical trial to evaluate the efficacy and safety of a food supplement " **FIBROLEX** "in patients with residual symptoms after having been sick with the viral infection Kovid-19
Main goal	1. Evaluation of the effectiveness of the use of a food supplement **FIBROLEX**. 2. Product safety.
Additional goals	Objective and subjective sensations when using the supplement / established with questions and **PATIENT DIARY**/ 2. Follow-up of patients, reporting of a period after which a result is established. 3. Follow-up of patients for the occurrence of unwanted side effects.
Study design	The current study will be open-label - all patients will receive the same doses of the product. **IMPORTANT!** **The product is taken orally!** - The daily dose is 3 capsules evenly distributed / 3x1 / during the day, which are taken for the entire period of the study / 20 days /. - Method of administration - 3 1 capsule 30 minutes before or 2 hours after a meal. - All products are provided to patients in person and free of charge and are distributed according to the protocol on the 1st / including visit - 30 capsules / and on the 10th day / second follow-up visit - 30 capsules /.

	1. The study will include three visits and, at the discretion of the Principal Investigator and the Sub-Investigator, a fourth follow-up visit.

THE RESEARCH

The study is aimed at 40 adults / 18-85 years / patients with residual symptoms after having been sick with the viral infection Kovid-19.

The laboratory results of all patients in the study were divided into two groups.

Group I - Patients in whom the observed values of d-dimer, CRP and LDH are normal throughout the study period.

Group II - Patients in whom the observed indicators d-dimer, CRP and LDH have high values on Day 1 / Visit 1 /. It is these patients that are monitored and analyzed in detail below.

In the laboratory tests performed on patients with high values of d-dimer, CRP and LDH on Day 1 / Visit 1 / and Day 20 / Visit 3 /, the following differentiation can be made in terms of development of indicators:

- 2 patients on day 1 / Visit 1 / gave high laboratory values / d-dimer, CRP, LDH above the norm /, on the 20th day / Visit 3 / these laboratory indicators are already normal.
- 3 patients, on day 1 / Visit 1 / have values above the reference for / d-dimer and LDH / and in norm for CRP, on day 20 all examined parameters are in norm / d-dimer, CRP, LDH /.
- 3 patients on day 1 / visit 1 / gave high laboratory values / d-dimer, CRP, LDH- above the norm /, on the 20th day / Visit 3 / the values of / CRP and LDH / are normal, and d -dimer remains high.
- 1 patient on day 1 and day 20 / Visit 1 and Visit 3 / gave laboratory values of d-dimer above normal, and CRP / LDH values were normal on both visits. Nevertheless, there is a decrease in d-dimer by 23% on Visit 3 / day 20 /.
- 1 patient per day 1 / Visit 1 / gave laboratory values of d-dimer above normal and CRP / LDH in normal. On day 20 / Visit 3 / Provides a laboratory result only for d-dimer, which is already normal.
- 1 patient per day 1 / Visit 1 / gave laboratory values of d-dimer above normal and CRP / LDH in normal. On day 20 / Visit 3 / Provides laboratory results in which all three monitored indicators are normal.

The following conclusions can be drawn from the monitored laboratory parameters.

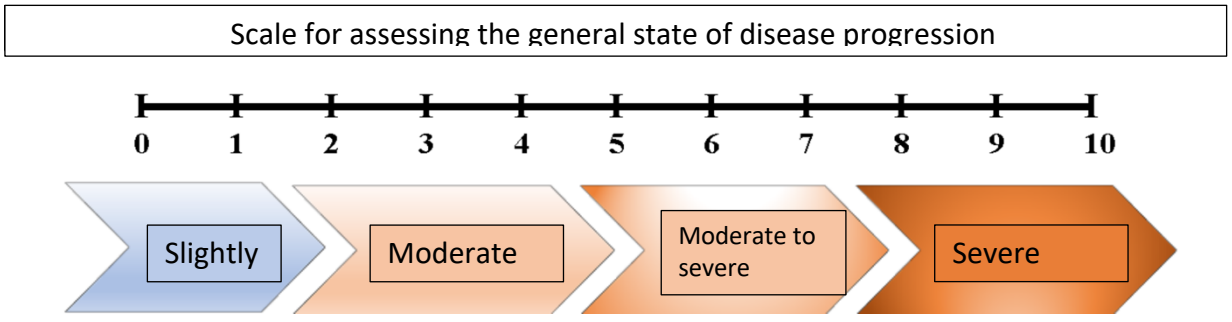
1. The average drop in D-dimer for the follow-up period (20 days) is 60%.
2. The average decrease in CRP for the follow-up period / 20 days / is 55%.
3. The average decrease in LDH for the follow-up period / 20 days / is 38%.

The following conclusions can be made on the basis of the monitored group / 10 people / of patients with high starting indicators / Day 1 - Visit 1 /.

1. 6 out of 10 patients with high D-dimer on day 1 / Visit 1 / returned to normal / Laboratory reference values / on Day 20 / Visit 3 /.
   In the patients who did not enter the reference values of Day 20 / Visit 3 / there was also a decrease in the indicators by an average of 39.3%.
2. 5 out of 5 patients with high CRP on day 1 / Visit 1 / returned to normal / Laboratory reference values / on Day 20 / Visit 3 /.
3. 8 out of 8 patients with high LDH on day 1 / Visit 1 / returned to normal / Laboratory reference values / on Day 20 / Visit 3 /.

CONCLUSIONS

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



1. 22 of the patients on the first visit considered to have a severe general condition of residual symptoms, 11 patients rated their symptoms as moderate and 7 patients as mild.

	Summary assessment of the overall course of residual symptoms in 40 patients at Visit 1			
	от 0 до 1	от 2 до 4	от 5 до 7	от 8 до 10
	mild	moderate	moderately severe	severe
patient assessment	**7**	**11**	**14**	**8**
doctor's assessment	**7**	**12**	**13**	**8**

2. At the second visit (day 10), the patients who considered themselves to have a severe general condition of residual symptoms were 15. There were 13 patients who rated their symptoms as moderate and 12 patients as mild.

	Summary assessment of the overall course of residual symptoms in 40 patients at Visit 2			
	от 0 до 1	от 2 до 4	от 5 до 7	от 8 до 10
	mild	moderate	moderately severe	severe
patient assessment	**12**	**13**	**15**	**0**
doctor's assessment	**12**	**14**	**14**	**0**

3. After the third visit (day 20), 22 patients considered themselves to be well, and 18 patients stated that the residual symptoms were still persistent, but in moderate levels.

	Summary assessment of the overall course of residual symptoms in 40 patients at Visit 3			
	от 0 до 1	от 2 до 4	от 5 до 7	от 8 до 10
	mild	moderate	moderately severe	severe
patient assessment	**22**	**16**	**2**	**0**
doctor's assessment	**21**	**17**	**2**	**0**

EVALUATION OF THE DOCTOR

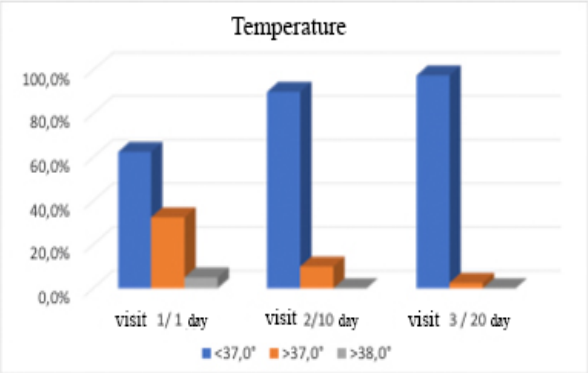
The evaluation of the doctor who performed the examination:

1. The subjective assessment described as "mild" by the patients during the three visits coincided with the assessment of the researcher who conducted the study.
2. The subjective assessment described as "Moderate" on all three patient visits was one point lower than that of the study researcher.

3. The subjective assessment by the patients "Moderate" of the first and second visits is 1 point higher than that of the researcher. At the third visit, the subjective assessment of the patients for the condition of the residual symptoms "Moderate" coincides with that of the researcher.
4. At all three visits, the patients' subjective assessment of "severe" coincided with that of the researcher.

II. Observed indicator TEMPERATURE

	Temperature in 40 patients / 18-85 years / by visits					
	visit 1/1 day	Pts	visit 2/10 day	Pts	visit 3/20 day	Pts
<37,0°	62,5%	25	90,0%	36	97,5%	39
>37,0°	32,5%	13	10,0%	4	2,5%	1
>38,0°	5,0%	2	0,0%	0	0,0%	0



1. Of the observed patients in terms of TEMPERATURE, 25 were with normal at inclusion, and 15 with increased, and only 2 of them with more than 38 degrees.

2. Second visit (10 days) from the beginning of the disease, 36 patients had a normal temperature and 4 patients had a low-grade fever.

3. Third visit / 20 days / only one patient remained with low-grade fever.

III. There is a symptom of TIREDNESS AND EASY FATIGUE

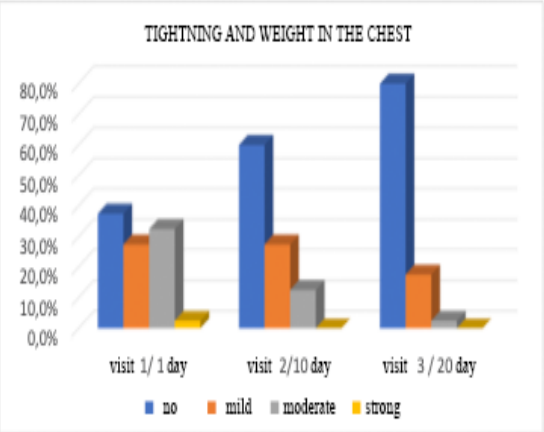
	fatigue and easy tiredness in 40 patients / 18-85 years / by visits					
	visit 1/1 day	Pts	visit 2/10 day	Pts	visit 3/20day	Pts
no	15%	6	30%	12	65,0%	26
mild	25%	10	30%	12	27,5%	11
moderate	25%	10	40%	16	7,5%	3
strong	35%	14	0%	0	0%	0

This symptom is strongly represented.

- Only 6 patients did not have this symptom at the first visit, while 24 patients reported moderate to severe and 10 reported mild "Tiredness and easy fatigue".
- At the second visit, 16 patients gave a subjective assessment of moderate symptoms, and a weak assessment of such symptoms in 12 patients.
- Only 3 patients gave a subjective assessment of "Moderate" at the visit 3/20 days /, 11 had a weak, and in 26 the symptoms disappeared.

IV. Observed symptom TIGHTNING AND WEIGHT IN THE CHEST

	TIGHTNING AND WEIGHT IN THE CHEST in 40 patients / 18-85 years / by visits					
	visit 1/1 day	Pts	visit 2/10 day	Pts	visit 3/20 day	Pts
no	37,5%	15	60,0%	24	80,0%	32
mild	27,5%	11	27,5%	11	17,5%	7
moderate	32,5%	13	12,5%	5	2,5%	1
strong	2,5%	1	0,0%	0	0,0%	0

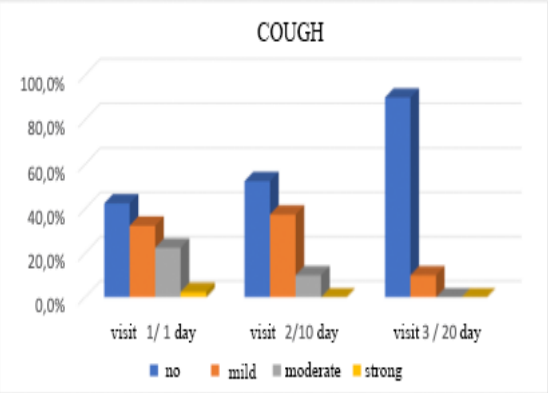


This symptom was not reported in 15 patients at the first visit.

- 24 patients gave a subjective assessment of "weak" to "moderate" strength of this symptom and only one as "strong".
- At the second visit (day 10) in 24 patients the symptom disappeared and in 11 patients it was mild. Only one patient gave a subjective assessment of "moderate" symptom strength.
- At the visit three / 20 days / already in 32 patients there is no symptomatology, in 7 patients it is weak, and in 1 it remains moderate.

V. Cough symptom was observed.

	COUGH in 40 patients / 18-85 years / by visits					
	visit 1/1 day	Pts	visit 2/10 day	Pts	visit 3/20 day	Pts
no	42,5%	17	52,5%	21	90,0%	36
mild	32,5%	13	37,5%	15	10,0%	4
moderate	22,5%	9	10,0%	4	0,0%	0
strong	3%	1	0%	0	0%	0

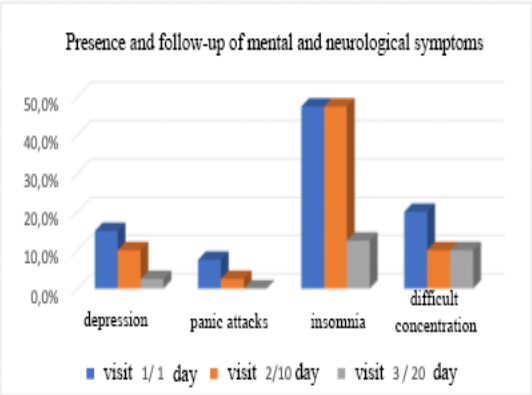


The symptom of cough in a strong form is present only in one patient at the first visit.

- 17 patients lacked this symptom at the start of the study, 13 had a mild cough and 9 had a moderate cough.
- On day 10 (Visit 2), the cough resolved in 21 patients, decreased significantly in 15 patients, and was still moderate in 4 patients.
- At the end of the study (3-day visit 20), only 4 patients had a residual mild cough, while the other participants (36) in the study had a mild cough.

VI. Symptom observed MENTAL AND NEUROLOGICAL SYMPTOMS

	Presence and follow-up of mental and neurological symptoms in 40 patients / 18-85 years / by visits					
	visit 1/1 day	Pts	visit 2/10 day	Pts	visit 3/20 day	Pts
depression	15,0%	6	10,0%	4	2,5%	1
panic attacks	7,5%	3	2,5%	1	0,0%	0
insomnia	47,5%	19	47,5%	19	12,5%	5
difficult concentration	20,0%	8	10,0%	4	10,0%	4



1. DEPRESSION

- At the first visit in 6 patients, the researcher reported the presence of this symptom.
- At the second visit (day 10), 4 patients showed signs of depression.
- At visit three (day 20), only one patient showed the presence of this symptom.

2. PANIC ATTACK

- On Visit 1 / day 1 / three patients reported that they had panic attacks, on Visit 2 their number decreased to 1, and on visit 3 / day 20 / there were no complaints from any of the participants.

3. INSOMNIA

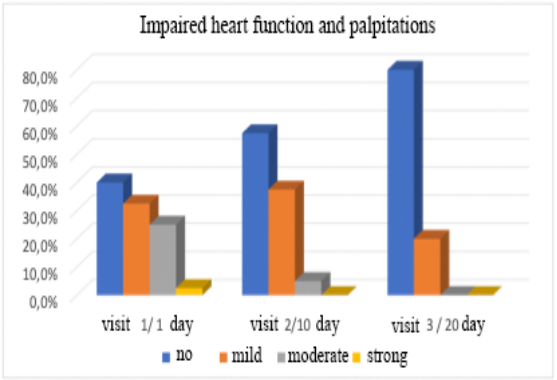
- This symptom is most common among study participants. Nearly half of the patients, and exactly 19 of them, declared on Visit 1 and Visit 2/10 days / that they suffer from insomnia. Improvement and reduction in the number of patients with this symptom was observed on Visit 3 / day 20 /, when insomnia persisted in only 5 of all participants.

4. DIFFICULT CONCENTRATION

- This symptom was present in 8 patients at the start of the study. After a decrease of 2 Visits / 10 days / to 4 patients who complain of difficult concentration, the number of participants affected by this symptom remains the same on the last 3rd Visit / Day 20 /.

VII. Observed symptom SYMPTOMS IN THE HEART ACTIVITY AND HEARTBEATING

	Impaired heart function and palpitations in 40 patients / 18-85 years / by visits					
	visit 1/1 day	Pts	visit 2/10 day	Pts	visit 3 / 20 day	Pts
no	40,0%	16	57,5%	23	80,0%	32
mild	32,5%	13	37,5%	15	20,0%	8
moderate	25,0%	10	5,0%	2	0,0%	0
strong	2,5%	1	0,0%	0	0,0%	0

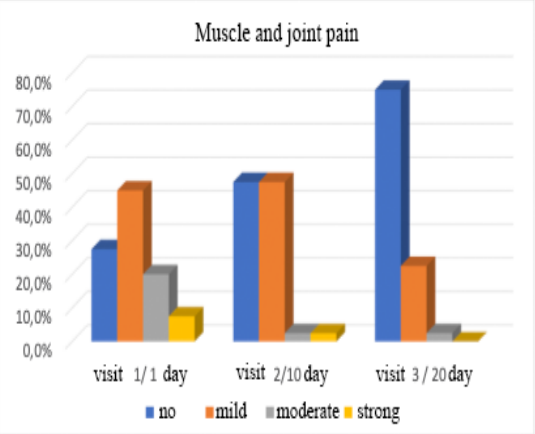


Only one patient complained of palpitations and cardiac abnormalities at the beginning of Visit 1.

- At Visit 1 / day 1/16 patients had no complaints regarding this symptom, 13 participants were mild and 10 were moderate.
- At Visit 2 (day 10), 23 had no more complaints, 15 had mild symptoms, and 2 patients still had symptoms of moderate severity.
- At Visit 3 / day 20/32 patients felt healthy and 8 participants complained of mild symptoms.

VIII. There is a symptom of PAIN IN THE MUSCLES AND JOINTS

	Muscle and joint pain in 40 patients / 18-85 years / by visits					
	visit 1/1 day	Pts	visit 2/10 day	Pts	visit 3/20 day	Pts
no	27,5%	11	47,5%	19	75,0%	30
mild	45,0%	18	47,5%	19	22,5%	9
moderate	20,0%	8	2,5%	1	2,5%	1
strong	7,5%	3	2,5%	1	0,0%	0



- At the beginning of the first day, 11 patients were without pain, 18 patients with mild, 8 with moderate and 3 with severe.
- At the visit 2/10 day / without pain are 19 patients, mild 19 patients and one with moderate and severe pain.
- At the visit, three / 20 days / 30 patients were without pain, 9 with mild and one with moderate.

EFFICIENCY

Evaluation of the effectiveness of the drug "Fibrolex" in 40 patients / 100% / based on average values by visits:

- At the second visit (day 10) of inclusion, 50% of patients were diagnosed without any residual symptoms.
- On the third visit / 20 days / from the inclusion the percentage of patients without complaints reaches 86%.

Important!

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

PATIENT SAFETY

At the end of the clinical trial, all 40 patients tolerated Fibrolex very well without complaints

June 27, 21 Unimed Medical Center