In the name of God

The final report of clinical trial in analysis of Osvalin® effectiveness in improvement of symptoms among patients with osteoarthritis of knee

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1. Introduction:

Osteoarthritis, which also called arthritis, is the most morbid articular diseases from which more than 20 million patients suffer in US. Osteoarthritis is assumed as the foremost reason for chronic disability in patient older than age 70 and it creates more than 100 million USD of cost for US (1).
Osteoarthritis may be deemed as a degenerative disease that occurs due to biochemical degeneration of cartilage (hyaline) of joint in synovial space. Nonetheless, it is mentioned today that Osteoarthritis is not only the disease of articular cartilage and it also includes total joint such as subchondral and synovial bone. Osteoarthritis generally makes the joints involved that tolerate body weight including knees, pelvis, backbones, and lower foot joints.
Although Osteoarthritis was already deemed as a disease caused by mechanical pressure and overweight on joints, the recent evidences indicate role of abnormal mechanisms and inflammation in incidence of this disease. However Osteoarthritis is classified as Chondral Non- Inflammatory Disease, many evidences have shown that

the inflammation takes place following to release of cytokines and metalloproteins into the joint. These materials may cause further degeneration of joint matrix and cartilage (2).
Symptoms of Osteoarthritis are as follows:
- Deep pain in the suffered joint that is intensified by activity (disease primary symptom)
- Reduced range of motion of the suffered joint
- Arthral stiffness during rest time (it may arise as mourning stiffness of joints that last for less than 30 minutes)
It is mentioned in etiology of this disease that daily stress on body joints and particularly the joints that undergo body weight (such as joints of knee, femur, and vertebrae) play essential role in their creation. There is this idea that the primary degenerative variations in osteoarthritis generally start in joint cartilage under influence of additional and frequent stress on healthy joints and or usual recursive stress on joints already injured. The external stress may intensify catabolic effects of chondrocytes and next degeneration of chondral matrix (3-5).
Some of the known risks in incidence of osteoarthritis are as follows (6-11):
- Age
- Obesity
- Trauma
- Genetic factors (family background of person)
- Muscular weakness
- Reduced rate of sexual hormones
- Frequent and double stress on joint
- Infections
- Acromegaly
- Crystal deposition
- Former history of chondral inflammatory arthritis
- Osteal disorders (Paget's disease of bone and so forth)
- Genetic metabolic disorders (Wilson's disease, hemochromatosis, and alkaptonuria etc.)
- Hemoglobinopathy cases (thalassemia and tuberculosis sickle anemia)
- Previous surgical history (e.g. meniscus surgery)
Following to rising age, the mass of cartilage in joint, proteoglycan content, rate of vessels (angiogenesis) in cartilages and their perfusion is reduced. These changes may lead to emerging radiologic expressions in joint such as stenosis of joint space but in any case the biochemical and physiopathologic findings have shown that the age may not solely act as an independent factor for morbidity of osteoarthritis.
More than 20 million persons suffer from osteoarthritis in US. This statistic may vary based on diagnostic criterion (clinical criteria or radiographic or combinatorial evidences of these methods), of course. The primary osteoarthritis is deemed as prevalent complication among old people and most of patients lack any symptom. Based on radiographic findings, more than 50% of person at age (>65) typically suffer from this disease to some extent (12). As usual, the symptoms appear after age 50 and morbidity of symptoms is dramatically increased after age 50. This morbidity with rising age is probably due to changes in content of collagen and proteoglycan in cartilages which reduce flexibility of cartilage and also it is due to reduced feeding in chondral tissue (13).
The primary awareness of patients with osteoarthritis depends on the involved joints as well as intensity of involvement. The following factors have been introduced as causing factors for quick disease progress in a systematic review (14):

- Old age
- High Body Mass Index (BMI)
- Varus deformity[1]
- Synchronous multiple chondral lesions (involvement)

Osteoarthritis is diagnosed according to clinical examinations and radiographic evidences and there is no diagnostic and exclusive laboratory disorder for it. In most of cases, there is no arrhythmia and warmth around joint but in acute cases, there may be restricted motion and atrophy of muscles around the joint (15). The researchers have utilized some cases including monoclonal antibodies, synovial liquid markers, and the products from chondral degeneration e.g. urinary pyridiniuim cross-links to diagnose osteoarthritis (16). But no marker could be solely effective in diagnosis of the given disease. The markers in acute phase in osteoarthritis are general at normal level. Usually Erythrocyte Sedimentation Rate (ESDR) is not increased in these patients. It may be possible for the level of erosive and inflammatory arthritis to be increased (17). The simple radiography of the selected diagnostic method is accompanied to clinical examination since it is cost-effective and at the same time it is quickly and simple available (18, 19). One of the diagnostic features in primary osteoarthritis is available in regions under joint stress and pressure in radiography where the arthral space is reduced in these areas and also subchondral bony sclerosis and formation of cyst may be seen.

In order to examine symptoms and disabilities of patients with osteoarthritis is deemed as the innovated and standardized clinical trial that has been used widely in assessment of patients with osteoarthritis for several years. This criterion is called in abbreviation form as WOMAC[2]. This criterion is a clinical criterion for treatment assessment in patients with osteoarthritis in knee joint or femur based on three symptoms pain (0-20), stiffness (0-8), and physical function of joints (0-68) (20, 21) (See also appendices).

Treatment of osteoarthritis:

The objective in treatment of osteoarthritis comprises of release of pain in patient, reduced inflammation, decreased disability, improvement of quality of life, and training of patients about their role in managing of their disease, and improving of his/her functional status. The treatment should be based on conditions and expectations of patient and function level and activity, the involved joints, disease intensity, occupational requirements, and the nature of any type of other background disease, and personalization.

Non-medicinal treatments usually start before treatment by drugs and they may include the following items:

- Training of patient
- Heating and cooling
- Reduced weight
- Physical exercise and physical therapies
- Occupational therapies
- Reduced stress on some specific joints such as knee and femur

The primary medicinal treatments start in those patients who do not respond to non-medicinal therapies. The important point is here that when patient lacks any symptom it does not generally necessitates for continuity of medicinal therapies since it has not

[1] - In orthopedics, a valgus deformity is a condition in which a bone or joint is twisted outward from the center of the body.

[2] - The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

so far proved that the drugs may influence in progressive trend of disease. Those drugs are used in treatment of osteoarthritis disease generally as follows:
- Acetaminophen
- Non-Steroid Anti-Inflammatory Drugs (NSAIDs)
- Intra articular glucocorticoids

Other drugs and supplements may be taken along with above drugs as auxiliary treatment. Type of therapy and drugs is selected according to intensity of disease, presence or absence of inflammation in joint, and effectiveness of therapy in previous episodes. There is no medicinal therapy so far that can improve nature of disease. Thus, medicinal therapies are basically focused on improvement of symptoms in patient (220.

Based on guidelines of therapies (23-25) in patient with osteoarthritis that lack inflammatory symptoms, the medicinal therapy initially starts as PRN (*pre-re-nata*) and if the adequate response is not received the drugs are administered 3-4 times as continuous dosage. If there is no adequate response or there are inflammatory symptoms, treatment is done by NSAID drugs. These drugs may be replaced by acetaminophen and or taken in combination with them. Similarly, topical dosage of NSAIDs and or capsaicin may be considered as alternative systemic therapy. In the patients for them their symptoms still remain despite of the above therapies and or dosage of NSAID is forbidden for them, it is recommended to use infusion of intra articular glucocorticoids. There is also a group of patients that did not respond to above primary therapies and they need to more advanced therapies. Some therapies including opioid painkiller, intra articular hyaluronic acid, glucosamine chondroitin compounds, and other drugs such colchicine in these patients may be taken duly (26). There are also other several therapies that have been adapted as supplements for improvement of osteoarthritis symptoms and there are some evidences regarding efficiency of them in patient with osteoarthritis.

Silicon is one of the efficient substances in health of bones (27-29). Silicon is an essential nutrient and shortage of this material leads to defect in skeletal growth phases (28, 30). Most of existing human and animal- based studies about role of Silicon for bones health are related to effectiveness of Silicon in recovery of osteoporosis and prevention from reduction of bone mass density (31). But some of studies in vitro and animal based researches have indicated that Silicon may be efficient in structure and health of cartilages. It was shown in an animal-based study on birds that deficit of silicon might reduce mass density of articular joint and this also decreases water content in tibial and femoral bones (32). It seems that Silicon plays role in bone and cartilage due to formation of organic matrix. Osteal and articular disorders are accompanied to reduction in matrix constituent elements where this issue implies necessity for Silicon in production of collagen and glucosamine glycan (33).

With respect to the existing evidences about role of Silicon in health of chondral tissue of joints, the present research explores the effects of administration of Silicon in improvement of symptoms among patients with osteoarthritis.

1-2- A review on texts:

The primary animal-based studies showed that Silicon might play positive role in bone mineralization process in rat mice. In a study that relevant findings were published in Science Journal, it was mentioned that Silicon might probably play role in metabolism of calcium as well (34, 35).

In 1993, Hott et al examined the effects of Silicon in organic solution (dosage: 1mg/kg) on trabecular bones at rats in which their wombs had been removed for one month. They found that administration of Silicon not only increased level of

osteoblasts in trabecular bones, but also decreased the level occupied by osteoclast of bone. This issue was led to increase bone mass in rats that have been treated by Silicon compared to control group (36).
Fewer studies have been carried out about effects of Silicon in bones health in human. Likewise, Eisinger et al administered Silicon in form of muscular infusion (50mg) twice a week for 4 months in females who suffered from osteoporosis and indicated that Silicon caused significant increase in Bone Mass Density (BMD) in therapeutic group compared to control group (37).
Jugdaohsingh et al (2004) reported in a study that the rate of receiving Silicon in nutrients might directly impact in rising Bone Mass Density (BMD) in pelvis among males and females before menopause and not in menopausal females (38). Similarly, in another study the positive relationship of nutrient Silicon supplements with rising BMD was shown in pelvis and backbone in female before menopause as well as menopausal females who were treated under Hormone Replacement Therapy (HRT) (39).Macdonald et al implied that estrogen might play role in metabolism and Silicon effects and these two factors might act as synergists (40). Nonetheless, this hypothesis may not explain effects of rising BMD in males who received Silicon. On the other hand, rate of receiving Silicon was low among menopausal females in these studies and none of these females had received more than 40mg/day silicon.
In a retrospective study that was conducted by Eisinger et al, administration of Silicon as supplement caused rising bone mass density in pelvis and vertebrae. The effects of Silicon were even greater than etidronate and sodium fluoride in this study as well (37). In other survey that was carried out by Spector et al in patients with osteoporosis and osteopenia, it was indicated that administration of orthosilicic acid could cause moving a trend toward rising density of bone formation (synthesis) markers in serum. The mild increase was also observed in bone mass density with low dosages (6mg/day) of silicon in this study (41).
No available human study was found about efficiency of Silicon in improving osteoarthritis symptoms.

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2- Design of study

2-1) Goals of study

2-1-1- Project major objective:

The analysis of positive effects of Osvalin® in improvement of symptoms in patients with osteoarthritis of knee joint

2-1-2- Project minor objectives:

- Review on immunity Osvalin® supplement in patients with osteoarthritis by follow-up the probable side effects in consumer patients in this study

2-2) Type of study:

This study is carried out as open and single-arm trial and without control group. The consequences of study were compared in patients under treatment before and after therapy by Osvalin® with their own.

2-3) Patients reception centers:

Rheumatology researching center of Dr. Shariati Hospital and Iran Rheumatism Center

2-4) Research population:

Patients with osteoarthritis in knee

2-5) Sampling

Following to the given coordination with patients in reception centers, the qualified patients (who possessed the study inclusion criteria and lacked the study exclusion criteria) were identified among the referent patients and after perfect briefing and taking written consent letter they were included in this study.

2-6) Response -to- therapy criterion or WOMAC criterion (The Western Ontario McMaster Universities Arthritis Index): It includes a clinical criterion for assessment of therapy in patients with osteoarthritis based on three symptoms: pain (0-20), stiffness (0-8), and physical function of joints (0-68).

2-7) inclusion and exclusion criteria:

2-7-1- Inclusion criteria for the studied participants:

- Patients at ages (18-80) with mild to medium osteoarthritis in knee who were under therapy by acetaminophen but did not adequate response to therapy

2-7-2- Exclusion criteria for the studied participants:

- Synchronous autoimmune diseases
- Nervous and mental diseases that make clinical trials as difficult
- Renal deficiencies (GFR<50ml/min)
- History of disease for rheumatoid arthritis, gout, chondrocalcinosis
- The presence of severe and progressive cardiovascular diseases (Class – 4)
- Presence of proved malignancy
- The existing important hepatic disease (esophageal varices and hemorrhage, encephalopathy, and ascites)
- Pregnancy and lactation
- Receiving intra articular drug dosage during three recent months
-Synchronous hip osteoarthritis
- Taking dosage of supplements in control of osteoarthritis during study
- Taking painkiller drug (rather than acetaminophen) and corticosteroid to control pain during studied period

2-8) Description of project implementation phases:

This type of clinical trial study was carried out to explore the helpful effects of Osvalin® supplemet in improvement of symptoms and intensity of disease among patient with osteoarthritis of knee. In this study, the qualified patients with inclusion criteria of study entered in this project after receiving consent letter with their awareness. The full information about type of study, the related goal, Osvalin®, and method of use and probable problems and conditions for participation in this study were explained to patients and deliberative written consent letter was received from them. 20 patients with osteoarthritis that were treated by acetaminophen but without controlling their symptoms completely were chosen and Osvalin® was administered to them with dosage of 1cc/25kg of body weight daily and vitamin C powder plus magnesium for one other day (according to instruction in brochure of manufacturing company). The rate of pain was measured in clinical examination based on 6 and 12 weeks after treatment (WOMAC criteria). This criterion is a clinical criterion for therapy assessment in patients with osteoarthritis based on three symptoms of pain (0-20), stiffness (0-8) and physical function of bone (0-68) that were introduced and standardized for the first time in 1988. If a patient was excluded from study for any reason, another patient entered in this study until 20 patients to be eventually and

perfectly complete this process while the reason for exclusion of any patient was recorded as well.
After primary visit by rheumatologist and final diagnosis of mild to medium osteoarthritis that does not need NSAID and lacked inflammation in joint, patients were introduced to Rheumatology Researches Center to include in the study. The primary experiments were done for the patient after reference to researches center and if s/he was qualified for inclusion criteria and lacked any exclusion criteria in this study, patient entered in this study. Any patient entered in this study after receiving answers of tests and taking consent letter with awareness from patient. Initially, tests and WOMAC criterion of patient were evaluated in baseline by the colleague physician in this project and recorded in Case Report Form (CRF) specified to any patient. Then after full description of method of taking product dosage, the patient was asked to refer to this center after 6 and 12 weeks after starting therapy for repeated checkup of tests and WOMAC criteria. If the patient encountered any problem or question about dosage of product or about process of study at any time during studied period and observed any specific side effects, s/he could call in the study colleagues by phone.
The patients were only allowed to take acetaminophen (PRN) to control pain during studied period. Therefore, patients with severe types of osteoarthritis that needed to receive therapies other than acetaminophen for control of pain were not included in this study. The patient was not allowed to take the supplement used in treatment of osteoarthritis such as glucosamine, arthrocin, Omega-3 etc. during studied period and since two week before starting this study, but is permitted to take calcium-D. If patient needs to take NSAID and or corticosteroid and does not respond to acetaminophen because of pain or inflammation s/he should be excluded from this project according to protocol of study.
To ensure from compliance of study implementation phases with the approved protocol this study was supervised by an informed observer and aware of study conditions. There was no predetermined timetable schedule for supervision over implementation phases and the observer kept continually in contact with the major executive of project to ensure from compliance of process of execution of study with the protocol.
The collected information in Case Report Forms (CRFs) included the following items:
- Demographic information and contact data of patients
- Vital symptoms (blood pressure, heartbeat, and breathing)
- History of previous diseases
- Full review of systems
- Paraclinical tests comprising: AST, ALT, SrCr, CRP, ESR, CBC

2-9) Consequences:

2-9-1- Primary consequence:

- Criteria variations in assessment of osteoarthritis of knee symptoms (WOMAC) during studied period

2-9-2- Secondary consequence:

- Variations in Pain part from WOMAC criteria only in patients
- Variations in Stiffness part from WOMAC criteria only in patients
- Variations in Physical Function part from WOMAC criteria only in patients
- Frequency and intensity of probable side effects during therapeutic period

2-10) Statistical methods

The collected data during study entered specific Case Report Form (CRF) and saved in computer information bank after final control and ensuring from their correctness.

Data analysis was carried out according to goals of study and by means of SPSS (vesion-21) software. One-way ANOVA test was employed along with Dunnett (Post-hoc) test to compare various times in a testing group after testing type of variables and with respect to type of variables and numbers of comparison times. Significance level was designated as ($p<0.05$).

3- Results:

3-1) Results of basic data

Patient reception phase in this clinical study was done from September 2015 to February 2016 and 24 patients entered in this study during this period out of them two patients were excluded from project because of identifying criteria for exclusion of study. Diagnosis of hip osteoarthritis was finalized for both of these patients at second visit and they were excluded from study. Also two other patients were excluded from study due to lack of referral to the clinic within stipulated times. None of patient was excluded from study because of incidence of side effect. Finally, 20 patient completed process of study and information of these patients was assessed and analyzed.

As it mentioned, the information from 20 patients who entered in the study as followings was analyzed:

- Totally, 2 patients were males (10.0%) and 18 patients were females (90.0%).
- The mean age in patients was 55.2±9.9 years (range of 42-63).

The basic data of patients in this study are given in Table 1:

Table 1: Basic specifications of patients

Patients characteristics	
Age (mean ± SD) years	**55.2±5.98**
Sex (M/F)	**2/18**
Weight (Kg) (mean ± SD)	**74.0±8.00**

The basic data were assessed in all of patients where some cases were explored before starting study and then in middle and final visits including vital signs (breathing, heartbeat, blood vessel, and body temperature), inflammatory factors, hepatic and renal function tests, erythrocyte counting (CBC) in all patients and all of these items were at reasonable level. Four patients suffered from mild anemia (Hg= 12-13g/dl) so no therapy was designated for them.

3-2) Results of therapeutic assessments:

As it implied in order to analyze effectiveness of Osvalin® in improvement of osteoarthritis symptoms, WOMAC clinical criterion was adapted and this criterion was measured before starting therapy and 6 and 12 weeks after treatment.

Compared to basic times, 6 and 12 weeks, a significant difference was observed among WOMAC criterion mean using one-way ANOVA test with statistic F=5.793 and P=0.005 within different periods.

The related results to middle period assessments (6weeks) and final period (12weeks) were compared by pairwise and two-sided form in post-hoc test using Dunnett test. These results showed significant difference and reduction of mean value of WOMAC criterion in patients at both mid-term period (P=0.030) and final period (P=0,004) compared to basic value.

The related information to analysis of WOMAC criteria is shown in Table 2.

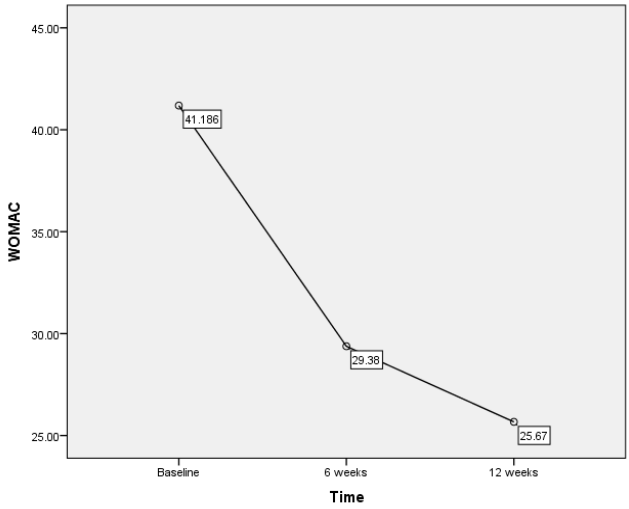
Table (2): Analysis on WOMAC mean- value at times 0, 6, and 12 weeks

Time	Mean WOMAC	Std. Deviation	95% Confidence Interval for Mean		Minimum	Maximum
			Lower Bound	Upper Bound		

Base	41.18	16.51	33.45	48.91	18.96	96.00
6 W	29.38	12.81	23.38	35.37	3.96	54.96
12 W	25.67	15.58	18.37	32.96	2.96	54.96

Trend of variance for final mean of sum of WOMAC criteria parameters is indicated in Diagram (1). As it mentioned, this mean-value showed reducing symptoms in patients. This value indicated significant reduction (P=0.030) 6 weeks after therapy by Osvalin® compared to baseline so that as it seen in this diagram, this decremental trend was also continued at 12th week after treatment and the significant level has been further reduced than baseline (P=0.004).

Diagram (1): Trend of variance in WOMAC mean criteria over the time



3-3) Changes in each of WOMAC criteria elements separately:

The trend of variance in each of three parameters of Pain, Stiffness (of joint), and Physical Function was separately analyzed using one-way ANOVA test. Two parameters of pain (of total score 20), and stiffness (of total score 8) were reduced during studied period in primary test as well as post-hoc test using Dunnett test but quantity of variance was not statistically significant (P=0.374 and P=0.342 at 12th week, respectively). But the variance of parameter of physical function (of total score 68) in WOMAC criterion was decremental and significant with statistic (F=3.426) in one-way ANOVA test and it was characterized in post-hoc test using Dunnett test that the rate of physical function (P=0.023) has been improved significantly compared to baseline at 12th week after therapy with Osvalin®.

The results of analysis on trend of variance in parameters of pain, stiffness (of joint), and variable of physical function were shown in Tables 3, 4, and 5, respectively.

Table 3: Analysis of variance for parameter of pain

Pain		Mean Difference	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
6 weeks	Baseline	-1.65	1.04427	.207	-4.0204	.7204
12 weeks	Baseline	-1.29	1.05792	.374	-3.6935	1.1093

Table 4: Analysis of variance for parameter of stiffness of joint

Stiffness	Mean Difference	Std. Error	Sig.	95% Confidence Interval

					Lower Bound	Upper Bound
6 weeks	Baseline	-1.80	1.36815	.323	-4.9031	1.3031
12 weeks	Baseline	-1.75	1.36815	.342	-4.8531	1.3531

Table 5: Analysis of variance for parameter of physical function

Physical Function Limitation Score		Mean Difference	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
6 weeks	Baseline	-5.55	3.43	.194	-13.3399	2.2399
12 weeks	Baseline	-8.90	3.43	.023	-16.6899	-1.1101

Similarly, variance for parameters of pain, stiffness of joint and physical function over this time was shown in Diagrams 2, 3, and 4, respectively.

Diagram 2: Trend of variance for parameter of pain during study

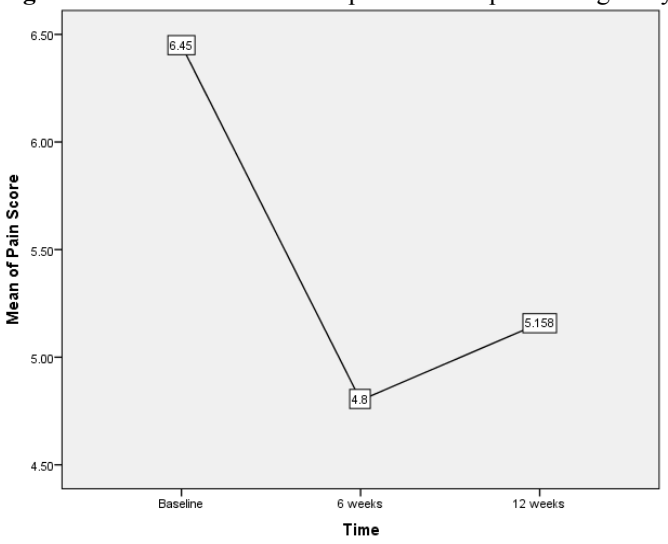


Diagram 3: Trend of variance for parameter of stiffness of joint during study

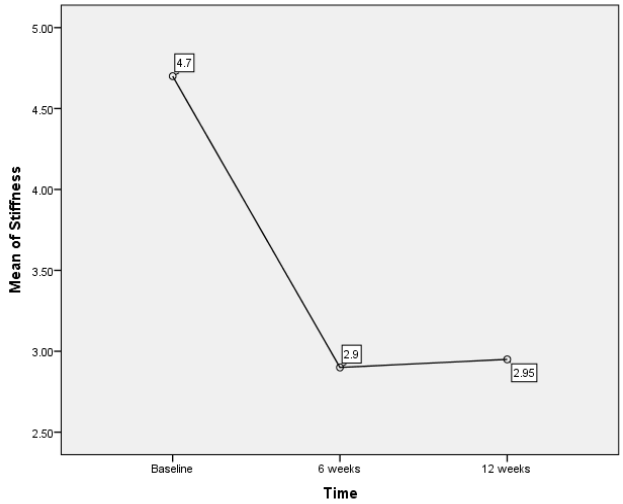
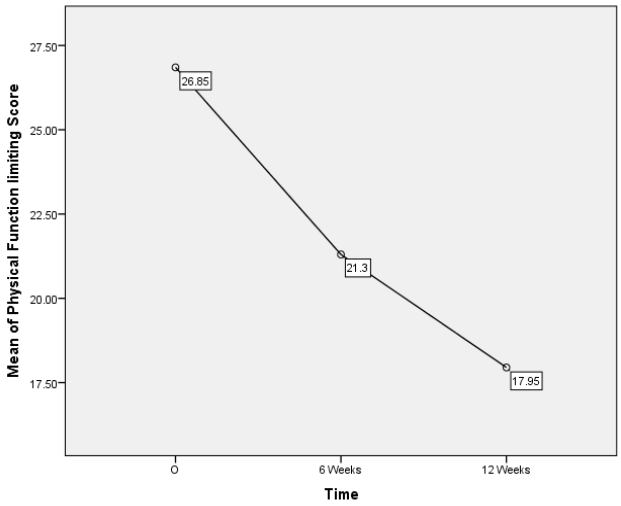


Diagram 4: Trend of variance for parameter of physical function during study



3-4) Side effects:

No obvious change was seen paraclinical tests of patients during studied period caused by side effect for dosage of Osvalin® supplement including biochemical tests including AST, ALT, SrCr, CBC diff. At tenth week after treatment, a patient reported intensification of pain in knee joint and tibia and it was because of this point that the given patient quitted dosage of Osvalin® but this problem was not identified as relating to Osvalin® in analysis of complication by panel of specialists in this study and it was reported as intensification of pains due to osteoarthritis for patient. No other lesion or complication was reported by the patients and at the same time it was not reported in medical examinations and reviews of medical colleague staffs in this study.

4- Discussion and conclusion:

The results of this study showed that dosage of Osvalin® in the group of patients with osteoarthritis of knee was immune and no specific side effect was identified in this investigation. Similarly, the results of this study indicated that following to dosage of Osvalin® the symptoms of osteoarthritis that were measured in patients including pain, physical function, and stiffness in WOMAC criteria were apparently improved by taking this product after 6 weeks where this improvement trend was also continued constantly and stably after about 3 months. Thus, it can be implied that probably taking Osvalin® supplement may contribute to improvement of mild to medium osteoarthritis symptoms in patients who did not only respond adequately to dosage of acetaminophen.

When WOMAC criterion was considered as general parameter for assessment of osteoarthritis symptoms, it was observed the symptoms in patients have been significantly improved in 6 and 12 weeks after therapy. But when each of WOMAC criterion segments was separately evaluated, only parameter of physical function was significantly improved at 12^{th} week; although there was some improvement in two other parameters (pain and stiffness of joint) but this difference was not statistically significant. The small sample size of patient may be a probable reason for this observation and if the studied sample size is increased, the rate of improvement in these parameters may become also significant separately.

The other point is that basically WOMAC criterion has been designed and standardized as a general index for assessment of symptoms of osteoarthritis and it should be analyzed as whole. In any case, with respect to findings of this study it can

be implied that effectiveness of Osvalin® has impacted more distinctively and positively on parameters of improvement of physical function among patients compared to parameters of pain and stiffness.

The present study is a type of prospective and single-arm research without control group and patients and medical staffs were informed about nature of the studied product. This study is a primary research that was conducted to analyze efficiency of Osvalin® in improvement of osteoarthritis symptoms. Thus, it can be expected that it comprises of the constraints of studies without control group. Until this day, this study is considered as the first clinical trial regarding effectiveness of Osvalin® in improvement of articular complications in patients with osteoarthritis that is deemed very important from this perspective. Of course, it necessitates for conducting further studies along with comparison with control group and greater sample sizes for the next and more accurate researches in the future. Similarly, patients may be treated under follow-up trend in larger studies for medical results over longer periods.

Appendices:

The sample form to use in WOMAC criteria assessment

WOMAC criteria **Final visit (at the end of 3-months therapy)**

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Full Name of Patient: **Date of Assesssment:**

scale of difficulty: **0** = None, **1** = Slight, **2** = Moderate, **3** = Very, **4** = Extremely

Circle **one number** for each activity

Pain	1. Walking	0 1 2 3 4
	2. Stair Climbing	0 1 2 3 4
	3. Nocturnal	0 1 2 3 4
	4. Rest	0 1 2 3 4
	5. Weight bearing	0 1 2 3 4
Stiffness	6. Morning stiffness	0 1 2 3 4
	7. Stiffness occurring later in the day	0 1 2 3 4
Physical Function	1. Descending stairs	0 1 2 3 4
	2. Ascending stairs	0 1 2 3 4
	3. Rising from sitting	0 1 2 3 4
	4. Standing	0 1 2 3 4
	5. Bending to floor	0 1 2 3 4
	6. Walking on flat surface	0 1 2 3 4
	7. Getting in / out of car	0 1 2 3 4
	8. Going shopping	0 1 2 3 4
	9. Putting on socks	0 1 2 3 4
	10. Lying in bed	0 1 2 3 4
	11. Taking off socks	0 1 2 3 4
	12. Rising from bed	0 1 2 3 4
	13. Getting in/out of bath	0 1 2 3 4
	14. Sitting	0 1 2 3 4
	15. Getting on/off toilet	0 1 2 3 4
	16. Heavy domestic duties	0 1 2 3 4
	17. Light domestic duties	0 1 2 3 4

Total Score: _____ / **96** = _____ %

Comments / Interpretation (to be completed by therapist only):