



The first Russian multicenter non-interventional registry study on the incidence of vitamin D deficiency and insufficiency in the Russian Federation in adults

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annotation

Target. Assess the frequency of vitamin D deficiency and insufficiency among the adult population living in the regions of the Russian Federation located at latitudes from 45 to 70°.

Materials and methods. Russian multicenter non-interventional registry study using the cross-sectional method.

Results. In the study, 72.1% of the surveyed have the status of vitamin D deficiency and insufficiency, while an adequate level was diagnosed in 27.8% of cases. When assessing the degree of vitamin D deficiency depending on the time of year, statistically significant differences ($p < 0.00001$) were found between periods: vitamin D deficiency or deficiency was observed in 84.2% of participants in spring and 62.4% in autumn. The highest frequency of vitamin D deficiency and insufficiency was recorded in males compared with women ($p = 0.013$, 79 and 70.3%, respectively). Vitamin D deficiency was observed in young people in the age subgroup of 18-25 years ($p < 0.001$, 54% in the study as a whole) significantly more often than in older people.

Conclusion. The ubiquitous high prevalence of low vitamin D sufficiency in the territory of the Russian Federation is not related to the geographic region of residence, but to a certain extent depends on the time of year. The high-risk group for vitamin D deficiency and insufficiency consisted of young men. The significant role of vitamin D in the human body justifies the need to supplement and clarify the unified concept for the prevention, diagnosis and treatment of conditions associated with deficiency, which emphasizes the relevance of introducing the obtained data into the National Clinical Guidelines.

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ORIGINAL ARTICLE

The first Russian multicenter non-interventional registry study to study the incidence of vitamin D deficiency and insufficiency in Russian Federation

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Abstract

Aim. To assess the incidence of vitamin D deficiency and insufficiency among the adult population living in the regions of the Russian Federation located at latitudes from 45 to 70°.

Materials and methods. Russian multicenter non-interventional registry study using the "cross-sectional" method.

Results. In this study, 72.1% of the examined have the status of vitamin D deficiency and insufficiency, while an adequate level was diagnosed in 27.8% of cases. When assessing the degree of vitamin D deficiency depending on the season, statistically significant differences ($p < 0.00001$) were found between the periods: vitamin D deficiency or insufficiency was observed in 84.2% of autumn and in 62.4% of spring. The highest

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incidence of vitamin D deficiency and insufficiency was recorded in males compared with females ($p=0.013$, 79 and 70.3% respectively). Vitamin D deficiency is observed in young people in the age subgroup of 18–25 years ($p<0.001$, 54% in the study as a whole) much more often than in older people

Conclusion. The widespread high prevalence of vitamin D deficiency in the Russian Federation is not related to geographic region of residence, but to some extent depends on the season. The high-risk group for vitamin D deficiency and insufficiency is young men. The significant role of vitamin D in the human body justifies the need to supplement and clarify a single concept for the prevention, diagnosis and treatment of conditions associated with deficiency, so higher implementation of National Clinical Guidelines is needed.

Keywords: vitamin D, deficiency and insufficiency 25(OH)D, prevalence, epidemiology **For citation:**

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Introduction

One of the global challenges for medical science and practice is the primary task of maintaining and strengthening the health of the population around the world. The relevance of the implementation of a preventive strategy as part of an integrated approach to increase life expectancy and improve the quality of life is reflected in the documents of the European Regional Office of the World Health Organization (Towards Health. European Strategy for the Prevention and Control of Noncommunicable Diseases, 2006), the United Nations [Political Declaration of the High Level Meeting of the UN General Assembly on the Prevention and Control of Noncommunicable Diseases (Resolution 66/2 of September 19, 2011)] and the Government of the Russian Federation (Federal Law of November 21, 2011 No. Russian Federation"1–3).

However, back in the 5th c. BC. Hippocrates, an ancient Greek physician and philosopher, wrote: "Some of the diseases come only from the way of life." Indeed, the state of human health is determined by many external and internal factors, the key role of which is played by the most common in the population. These key, modern predictors that determine "health" include

vitamin D deficiency. From the point of view of fundamental knowledge, vitamin D is the foundation for adult health, which is laid at the very beginning of the future life, from the point of view of large-scale studies of the past three decades, it is the most important micronutrient, the deficiency of which is considered as a global problem, not only because of its widespread, but also because of the close association with numerous pathological processes and severe medical and social diseases [1–6].

Despite the close attention of scientists to the role of vitamin D in the human body, the issue of its widespread deficiency around the world is still extremely acute. The scale of the problem is emphasized by Russian and international clinical and epidemiological studies.

studies demonstrating that from 50 to 92% of the adult population have low levels of 25(OH)D in the blood serum, regardless of the season [7–12], and according to some data, this figure reaches 100% [13]. Russia is unique in terms of research focused on the features of the territory - it is the largest country in the world with a wide range of geographic regions and a wide variety of weather and climatic conditions. It should be noted that the studies conducted in various geographical areas of the Russian Federation are fragmented and heterogeneous. It is the lack of unified massive epidemiological studies of the frequency of vitamin D deficiency and insufficiency that does not allow clarifying its true prevalence in the Russian Federation.

The purpose of the study is to assess the frequency of vitamin D deficiency and insufficiency among the adult population living in the regions of the Russian Federation located at latitudes from 45 to 70°.

Materials and methods

Study design. Russian multicenter non-interventional registry study according to the method cross sections. Carried out in two periods: March-May (spring) and October-November (autumn) 2020. Primary endpoints included the study of the level of 25(OH)D in the blood serum of volunteers in various geographical regions and the determination of the level of 25(OH)D in blood serum depending on the season. Secondary endpoints are the demographic characteristics of study participants (gender, age). Recruitment and questioning of study participants were carried out on the basis of the medical offices of Invitro LLC.

In general, for two periods (spring and autumn 2020), the study included 996 subjects from 10 regions of the Russian Federation (Moscow, Rostov-on-Don, St. Petersburg, Murmansk, Yekaterinburg, Tyumen, Kyzyl, Vladivostok, Norilsk, Novosibirsk). The largest number of volunteers was recruited in Moscow (109 people) and St. Petersburg (106 people),

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¹Recovery course. European strategy for the prevention and control of noncommunicable diseases, WHO, 2006. Access mode: https://www.euro.who.int/__data/assets/pdf_file/0010/76528/E89306R.pdf. The link is active on 09/17/2021.

²Political Declaration of the High-Level Meeting of the General Assembly on the Prevention and Control of Noncommunicable Diseases. Adopted by resolution 66/2 of the General Assembly on 19.09.2011. Access mode: http://www.un.org/en/documents/decl_conv/declarations/diseases_politdecl.shtml. The link is active on 08/28/2018. Federal

³Law "On the fundamentals of protecting the health of citizens in the Russian Federation" dated November 21, 2011 No. 323-FZ (last edition). Access mode: http://www.consultant.ru/document/cons_doc_LAW_121895/ The link is active on 09/17/2021.

Table 1. Distribution of study subjects by geographic regions (for the study as a whole)

Table. 1. Distribution of study subjects by geographic region (overall across the study)

Geographic region	Men	Women	Total
Vladivostok	23	74	97
Yekaterinburg	24	73	97
Western Arctic	19	79	98
Red	21	74	95
Moscow	16	93	109
Novosibirsk	14	85	99
Norilsk Rostov-	28	69	97
on-Don St. Petersburg	18	78	96
	21	85	106
Tyumen	26	76	102
Total in study	210	786	996

the smallest - in Kyzyl (95 people) and Rostov-on-Don (96 people); **tab. 1.** The study group consisted of healthy volunteers who signed informed consent to participate in the study.

Criteria for inclusion in the study:

- 1) male and female volunteers aged from 18 to 50 years old inclusive;
- 2) body weight over 45 kg and not more than 100 kg included effectively;
- 3) the presence of a signed form of informed consent to participate in the study.

Exclusion criteria:

- 1) the volunteer is currently participating in some other clinical trial;
- 2) the volunteer takes medicines or biologically active supplements containing vitamin D, in the form of monopreparations or combinations of vitamin D with calcium;
- 3) clinical signs of malabsorption syndrome at the time of screening (for example, diarrhea, abdominal pain, asthenovegetative syndrome, etc.);
- 4) pregnancy or breastfeeding period;
- 5) the inability of the volunteer, in the opinion of the employee of the research center, to fulfill the conditions of this study;
- 6) other conditions that, in the opinion of the employee investigation center, prevent the inclusion of a volunteer in the study.

The study of blood serum for 25(OH)D was carried out by the method of chemiluminescent immunoassay for microparticles in the centers of Invitro LLC. According to the recommendation of the Russian Association of Endocrinologists in 2015, the level of 25(OH)D was taken as adequate at ≥ 30 ng/mL (≥ 75 nmol/L), deficiency - ≥ 20 and < 30 ng/mL (≥ 50 and < 75 nmol/l), deficiency - < 20 ng/ml (< 50 nmol/l).

Statistical analysis was carried out using specialized software StatSoft Statistica and included the evaluation of the following parameters: analysis of laboratory data and demographic indicators. Descriptive statistics of quantitative traits are represented by medians (*Me*). When comparing two independent groups on a quantitative basis to assess

statistical significance of intergroup differences

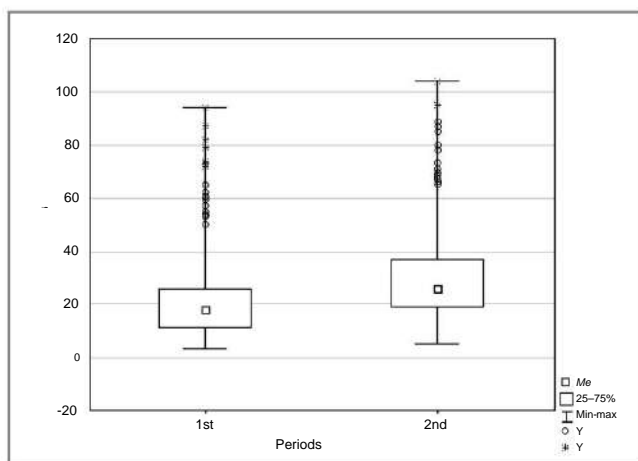
Mann-Whitney U-test (U) was used. The relationship of quantitative variables was estimated using the Spearman correlation coefficient. To compare the groups on a qualitative basis, we used the calculation of the 95% confidence interval for the odds ratio and Pearson's χ^2 test. In order to clarify the demographic characteristics that affect the presence or absence of vitamin D deficiency, correlation analysis was used, as well as generalized discriminant analysis. In each group, it was planned to stratify the participants by sex in the ratio: men - 46%, women - 54%, which corresponds to the percentage distribution of the population of the Russian Federation by gender. In case of deviation from the specified ratio in one or several geographic regions, the procedure of statistical weighting of data was carried out taking into account the actual distribution by sex in this geographic region according to the data of the Federal State Statistics Service "Population of the Russian Federation by sex and age"⁴. The critical level of significance in testing statistical hypotheses was assumed to be 0.05.

This study was conducted strictly in accordance with the ethical principles proclaimed in the Declaration of Helsinki, ICH GCP (ICG QCP - Rules for Good Clinical Practice developed by the International Conference on Harmonization), and the current legislation of the Russian Federation. Study protocol No. AQ-01/20, version 2.0 dated February 25, 2020, was approved by the Independent Interdisciplinary Committee for Ethical Review of Clinical Research.

results

Primary endpoints: study of the level of 25(OH)D in the blood serum of volunteers in various geographic regions; determination of the level of 25(OH)D in the blood serum depending on the season. The study assessed the frequency of deficiency and insufficiency of vitamin D in different regions of the Russian Federation, which represent a geographically representative sample with a high risk of developing a low level of vitamin D sufficiency. Based on the results of monitoring the frequency of deficiency and insufficiency of vitamin D, that the level is 25(OH)D,

⁴ Access mode: <https://www.gks.ru/compendium/document/13284>. The link is active on: 02/10/2020.



Rice. 1. Diagram of the range of 25(OH)D concentrations over the study periods.

Fig. 1. Peak diagram of 25(OH)D concentrations by study periods.

equal to less than <20 ng/ml, was registered in 39.3%, the interval of 25(OH)D $\dot{y}20$ and <30 ng/ml was detected in 32.8% of volunteers. In general, 72.1% of the examined had the status of vitamin D deficiency and insufficiency, while an adequate level was diagnosed in 27.8%. Since the observed distribution of study participants by gender differs from that of the population of the Russian Federation in the analyzed geographic regions, the procedure for statistical weighting of the data was carried out, taking into account the actual distribution by sex.

In this geographic region. Statistically weighted, 39% of cases were vitamin D deficient, 71.9% were vitamin D deficient or deficient, and thus only 28% of the study population had adequate levels. The highest percentage of subjects with vitamin D deficiency was observed in Kyzyl (67.3%), the lowest in Vladivostok (21.6%). The percentage of subjects with vitamin D insufficiency or deficiency ranged from 60.8% (Vladivostok) to 86.3% (Kyzyl); **tab. 2**. In the study

The study assessed the degree of vitamin D deficiency depending on the time of year. When comparing the data for the 1st (spring) and 2nd (autumn) periods, significant statistically significant differences ($p < 0.00001$, Pearson's χ^2 test) were revealed between the periods: vitamin D deficiency or deficiency was observed in 84.2% participants in spring (**Table 3**) and 62.4% in autumn (**Table 4**).

Differences in median concentrations of 25(OH)D in blood serum in spring (18 [11; 26] ng/mL) and autumn (26 [19; 37] ng/mL) are statistically significant ($p < 0.000001$, Mann-Whitney). The range of 25(OH)D concentrations over the study periods is shown in **Fig. 1**.

Secondary endpoints: demographic characteristics (sex, age). The study of basic demographic characteristics, such as gender and age, was the next stage of the study.

When evaluating gender characteristics, it was found that males are characterized by a higher frequency of low vitamin D levels compared to women ($p = 0.013$, 79 and 70.3%, respectively); **tab. 5**. Vitamin D deficiency was observed in young people in the age subgroup of 18-25 years ($p < 0.001$, 54% in the study as a whole) significantly more often than in older people. Insufficiency or deficiency of vitamin D in this age subgroup was detected in 79.1%. After statistical weighting of the data, in Russia as a whole, 81.3% of young people aged 18-25 experience vitamin D deficiency or deficiency compared to other age groups (**Table 6**).

Discussion

Back in the 1960s-80s of the XX century. A group of researchers led by H. De Luca studied in detail the metabolism of vitamin D. Two sources of vitamin D intake into the human body are known for certain - from food and as a result of synthesis in the skin under the influence of ultraviolet rays. To date, the scientific literature is actively discussing such terms as "sun-catching behavior" and "vitamin D-oriented diet" [14]. The former refers to walks on sunny days in the fresh air, while the latter refers to the active inclusion in the diet of foods that are richest in vitamin D. However, both of these pathways have

Table 2. Summary table of study results after "weighting" the data: the proportion of patients with deficiency, insufficiency or normal levels of vitamin D, taking into account the distribution by geographical region (overall for the study)

Table 2. Summary study results table after "weighing" the data: the proportion of patients with deficiency, lack or normal levels of vitamin D with respect to the distribution by geographic regions (overall across the study)

Geographic region	In the study as a whole, the level of 25(OH)D in the blood serum								According to the Russian Federation in general
	Ecate Rinburg	Western Arctic	Red Moscow	Novosibirsk	But rilsk	Rostov-on-Don	St. Petersburg	Tyu less	
	46:54	47:53	48:52	46:54	47:53	47:53	46:54	47:53	48:52 46:54
Shortage, %	39,4	33,4	67,3	38,8	37	39,7	40,2	43,1	31 39
Insufficiency, %	27,5	42,9	18,8	28,7	37,5	34	30,2	38	31,6 32,9
Rate, %	33	23,5	13,8	32,4	25,4	26,1	29,5	18,7	37,3 28
Insufficiency or deficiency in total,%	66,9	76,4	86,1	67,5	74,5	73,8	70,4	81,2	62,6 71,9
Total participants, abs.	97	98	95	109	99	97	96	106	102 996

Table 3. Summary table of study results: proportion of patients with deficiency, insufficiency or normal levels of vitamin D, taking into account the distribution by geographical regions (1st period - spring 2020)

Table 3. Summary study results table: the proportion of patients with deficiency, lack or normal levels of vitamin D with respect to the distribution by geographic regions (1st period – 2020 spring)

		First study period										
		Geographic region										
Serum 25(OH)D level		Authorities East	Ecate rin burg	West noe Start Let's play	Ky call	We squa	But guardian Birsk	But rilsk	Rostov-on-Don	St. Petersburg	Tyu less	Total
deficit*	abs.	13	26	23	37	27	24	22	31	29	19	251
	%	29,5	61,9	50	82,2	60	54,5	51,1	73,8	61,7	40,4	56,4
The lack accuracy	abs.	20	10	20	4	12	12	13	8	14	11	124
	%	45,4	23,8	43,4	8,8	26,6	27,2	30,2	19	29,7	23,4	27,8
Norm	abs.	11	6	3	4	6	8	8	3	4	17	70
	%	25	14,2	6,5	8,8	13,3	18,1	18,6	7,1	8,5	36,1	15,7
Insufficient accuracy or total deficit	abs.	33	36	43	41	39	36	35	39	43	30	375
	%	75	85,7	93,4	91,1	86,6	81,8	81,4	92,8	91,4	63,8	84,2
Total participants	abs.	44	42	46	45	45	44	43	42	47	47	445

*Here and further in Table. 4: Vitamin D deficiency is defined as a 25(OH)D concentration <20 ng/mL (50 nmol/L), deficiency as a 25(OH)D concentration of 20 to 30 ng/mL (50 to 75 nmol/L), adequate levels - more than 30 ng / ml (75 nmol / l).

Table 4. Summary table of study results: Proportion of patients with deficiency, insufficiency or normal levels of vitamin D, taking into account the distribution by geographical region (2nd period - autumn 2020)

Table 4. Summary study results table: the proportion of patients with deficiency, lack or normal levels of vitamin D with respect to the distribution by geographic regions (2nd period – 2020 autumn)

		Second study period										
		Geographic region										
Serum 25(OH)D level		Vla miracle stock	Ecate rin burg	West noe Zapolya eat	Ky call	We squa	But guardian Birsk	But rilsk	Rostov-on-Don	St. Petersburg	Tyu less	Total
deficit*	abs.	8	12	10	27	16	13	17	8	17	13	141
	%	15	21,8	19,2	54	25	23,6	31,4	14,8	28,8	23,6	25,5
The lack accuracy	abs.	18	17	22	14	19	25	20	21	26	21	203
	%	33,9	30,9	42,3	28	29,6	45,4	37	38,8	44	38,1	36,8
Norm	abs.	27	26	20	9	29	17	17	25	16	21	207
	%	50,9	47,2	38,4	18	45,3	30,9	31,4	46,3	27,1	38,1	37,5
The lack accuracy or total deficit	abs.	26	29	32	41	35	38	37	29	43	34	344
	%	49	52,7	61,5	82	54,6	69	68,5	53,7	72,8	61,8	62,4
Total involved cov	abs.	53	55	52	50	64	55	54	54	59	55	551

a number of restrictions. The contribution of nutrition to an adequate level of vitamin D supply is small, this is due to the fact that there are very few natural dietary sources of this micronutrient in the daily diet [15]. Significantly more important is the endogenous pathway of formation

vitamin D, directly dependent on the geography of the territory and the activity of solar radiation. Assessing the climatic and geographical conditions of the Russian Federation, it can be confidently stated that vitamin D deficiency is a widespread problem. Confirmation of the given data

Table 5 Proportion of patients with deficiency, insufficiency or normal levels of vitamin D by sex (overall study)

Table 5. The proportion of patients with deficiency, lack or normal levels of vitamin D with respect to the distribution by gender (overall across the study)

Serum 25(OH)D level		Men	Women	Generally by research
Deficit	abs.	103	289	392
	%	49	36,7	39,3
Failure	abs.	63	264	327
	%	30	33,5	32,8
Norm	abs.	44	233	277
	%	20,9	29,6	27,8
Insufficiency or deficiency in total	abs.	166	553	719
	%	79	70,3	72,1
Total participants	abs.	210	786	996

Table 6. Summary table of study results after "weighting" the data: the proportion of patients with deficiency, insufficiency or normal levels of vitamin D, by age groups (total for the study)

Table 6. Summary study results table after "weighting" the data: the proportion of patients with deficiency, lack or normal levels of vitamin D with respect to the distribution by age groups (overall across the study)

Age group, years Male:female	18–25	26–30	31–35	36–40	41–45	46–50
ratio Deficit, %	51:49	51:49	50:50	51:49	48:52	48:52
	56,3	45,4	37,5	37,5	32,7	34,3
Deficiency, %	25	32	38,2	28,9	32,1	32
Norm, %	18,6	22,5	24,2	33,5	35,1	33,6
Insufficiency or deficiency in total, % Total participants,	81,3	77,4	75,7	66,4	64,8	66,3
abs.	211	189	193	152	132	119

There may be several key points. First, most of the territory of the Russian Federation is located north of 35° north latitude, in a zone of insufficiently intense solar insolation [16]. In addition, most settlements are characterized by a small number of sunny days per year (no more than 40–70). Second, the natural photoproduction of vitamin D in the skin depends on a number of factors: the angle of incidence of sunlight, the season of the year, cloudiness, atmospheric pollution, daylight hours, and time spent outdoors [17, 18].

In recent years, more than 5 thousand epidemiological studies have been conducted in different countries of the world to study the status of vitamin D. These studies have shown that vitamin D deficiency is widespread in all age groups, in all geographic latitudes and occurred regardless of the season [19–21]. According to the results of the study, 72.1% of volunteers were diagnosed with vitamin D deficiency and insufficiency, thus, every 7th out of 10 surveyed has a low level of 25(OH)D, regardless of the season of the year and region of residence. Significant statistically significant differences between the two research

mi periods. It was shown that in the spring period of the study, low vitamin D status was significantly more frequently recorded than in the autumn months. It should be emphasized that the results obtained are fully consistent with previously published work. The first mention of seasonal fluctuations in vitamin D dates back to 1974, when McLaughlin et al. showed results with

according to which the peak levels of 25(OH)D were recorded in the autumn months and were not associated with a change in the nature of nutrition or additional intake of vitamin D [22]. To date, there are fairly convincing data on the seasonal concentration of 25(OH)D. In several studies, it was reliably noted that the level of 25(OH)D decreases by the onset of the winter period compared to the summer months [23, 24]. The lowest concentrations of 25(OH)D were found in the inhabitants of the northern hemisphere in the spring months of the year, when the reserves are completely depleted.

sy vitamin D, synthesized in the previous summer [25]. First of all, this is explained by the fact that these territories are located in the zone of deficiency of solar exposure, which is why in the northern regions the synthesis of vitamin D in the skin does not occur at all from 4 to 6 months per year [26, 27]. Nevertheless, the data obtained reliably emphasize that, with a combination of unfavorable climatic and geographical factors, the amount of vitamin D synthesized in the skin under the action of solar radiation is significantly

decreases.

Undoubtedly, the study of the prevalence of vitamin D deficiency and insufficiency is necessary for the formation of a risk group in order to conduct targeted biochemical screening. The study also assessed key demographic characteristics and noted a higher percentage of men with low 25(OH)D levels, as well as in the 18 to 25-year-old subgroup of young adults. It is important to note that the data obtained do not correlate with previously published studies [11, 28]; perhaps

this is due to the limitations of this study, such as a small sample size in general and in terms of a particular region, an upper age limit of 50 years, and a disproportion of participants included in the study by gender. Also, the information obtained may indicate a global change in the nutrition paradigm of the population towards the “crowding out effect” of foods rich in essential vitamins and micronutrients. In this regard, vitamin D is no exception. An active fortification policy for vitamin D fortification in foods can serve as a unique natural way to prevent vitamin D deficiency.

Taken together, the new data obtained determine the prospects for further study of the prevalence of vitamin D deficiency and insufficiency in the Russian Federation to supplement and clarify the high-risk group for vitamin D deficiency. prevention and treatment of vitamin D deficiency, as well as to create an optimal preventive program and therapeutic tactics for the population as a whole, which is an important tool

volume of prevention, promotion of health and improvement of the quality of life of the population [29].

Conclusion

The ubiquitous high prevalence of low vitamin D sufficiency in the Russian Federation is not related to the geographic region of residence, but to a certain extent depends on the time of year. The study shows a higher prevalence of vitamin D insufficiency and deficiency in spring than in autumn. The high-risk group for vitamin D deficiency and insufficiency consisted of young men. To correct vitamin D deficiency, there is a fairly wide range of preparations containing cholecalciferol, but most of the

The most widely used drugs on the domestic market are dietary supplements, while only the medicinal product has registered indications for the treatment of vitamin D deficiency and insufficiency. Since vitamin D is a fat soluble vitamin, the main mechanism of its absorption in the gastrointestinal tract, like other fat soluble vitamins, is micellization. The use of a preparation based on a micellar solution of cholecalciferol (Aquadetrim®) ensures a good degree of absorption, regardless of the composition of food, medication or the state of the gastrointestinal tract. Aquadetrim® in the form of dissolvable tablets is a convenient form of vitamin D that can be dissolved either in the mouth or in a small amount of water. The significant role of vitamin D in the human body justifies the need to supplement and clarify a unified concept for the prevention, diagnosis and treatment of conditions associated with deficiency, which may be reflected in the National Clinical Guidelines.

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