VITAMIN D DEFICIENCY IN RUSSIA: FIRST RESULTS OF A REGISTRY NON-INTERVENTIONAL STUDY OF THE FREQUENCY OF VITAMIN D DEFICIENCY AND INSUFFICIENCY IN DIFFERENT GEOGRAPHICAL REGIONS OF THE COUNTRY

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RATIONALE. In the Russian Federation, there are no large-scale, cross-sectional, multicenter epidemiological studies evaluating the prevalence of vitamin D deficiency and insufficiency in different geographic latitudes. Insufficient solar insolation and inadequate vitamin D content in food products dictate the need to study the epidemiological structure of low vitamin D status in Russia.

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

MATERIALS AND METHODS. The first stage of the Russian multicenter non-interventional registry study using the "cross-sections" method was carried out from March 2020 to May 2020.

RESULTS. In the regions of the Russian Federation, which represent a geographically representative sample with a high risk of developing low levels of vitamin D, its deficiency was noted in 55.96%, and the level of deficiency and insufficiency was recorded in 84.01%.

CONCLUSION. Close attention to the wide scale problem of vitamin D deficiency and insufficiency in the Russian Federation will contribute to the progressive formation of various educational and preventive programs necessary to improve health and improve the quality of life of the population.

KEYWORDS: vitamin D; prevalence; epidemiology.

VITAMIN D DEFICIENCY IN RUSSIA: THE FIRST RESULTS OF A REGISTERED, NON-INTERVENTIONAL STUDY OF THE FREQUENCY OF VITAMIN D DEFICIENCY ANDÿINSUFFICIENCY IN VARIOUS GEOGRAPHIC REGIONS OF THE COUNTRY

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BACKGROUND. In Russian Federation, there are no large-scale cross-sectional multicenter epidemiological studies assessing the prevalence of vitamin D deficiency and insufficiency in different geographical latitudes. Insufficient solar insolation and inadequate vitamin D content in food dictate the need to study the epidemiological structure of low vitamin D status in Russia.

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

MATERIALS AND METHODS. The first stage of the Russian multicenter non-interventional registry study using the «cross sectional» method was carried out from March 2020 to May 2020.

RESULTS. In regions that represent a geographically representative sample of regions of the Russian Federation with a high risk of developing low levels of vitamin D, it's deficiency was noted in 55.96%, and the level of deficiency and insufficiency was recorded in 84.01%.

CONCLUSION. Close attention to the wide scale of the problem of vitamin D deficiency and insufficiency in the Russian Federation will contribute to the progressive formation of various educational and preventive programs necessary to strengthen health and improve the quality of life of the population.

KEYWORDS: vitamin D; prevalence; epidemiology.

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RATIONALE

In the process of enrichment of fundamental scientific data on the significance of vitamin D deficiency for human health, the horizons of its clinical application in practical medicine were expanded. The history of vitamin D research began on the eve of the 20th century. and continues to this day. At present, vitamin D has a fantastic trajectory of a hundred years from "vitamins for bone growth", used exclusively in pediatric practice, to the main goal of large-scale comprehensive genome-wide research, which makes a significant contribution to the prevention and treatment of a wide range of socially significant diseases [1–6]. However, despite its century-old research history, the accumulated clinical experience of using vitamin D in various fields of medical science and public health practice, as well as its integral contribution to the state of public health, the problem of widespread vitamin D deficiency remains colossally acute throughout the world [7]. The climatic and geographical features of the region of residence play a key role in the development of vitamin D deficiency and insufficiency in the local population. This is explained by the fact that vitamin D deficiency is widespread in areas located in northern latitudes (above 35° N), where, due to low average annual temperatures, a small number of sunny days, and an acute angle of incidence of sunlight and their dispersion in the upper layers of the atmosphere in the autumn-winter and early spring period, contact with the skin is tangential, which significantly reduces the possibility of adequate production of vitamin D [8]. The world practice of multicenter population-based studies confirms the high incidence of pandemic low vitamin D status among all age groups; this information is also reflected in the results of Russian studies conducted with an eye to different geographic latitudes [9–18]. At the same time, the available data are insufficient for a full-scale assessment and a comprehensive epidemiological characterization of the prevalence of vitamin D deficiency and insufficiency in the territory of the Russian Federation (RF). In addition, their combined analysis is very difficult due to the lack of a unified strategic concept of published studies.

PURPOSE OF THE STUDY

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

MATERIALS AND METHODS

Place and time of the study

Location. RF. Regions located in latitude from 45° to 70° (Moscow, Rostov-on-Don, St. Petersburg, Murmansk, Yekaterinburg, Tyumen, Kyzyl, Vladivostok, Norilsk, Novosibirsk).

Research time. The first phase of the study will include the spring period began from March 01, 2020 to May 31, 2020.

Studied populations

population. Healthy Volunteers (Volunteers who reported, at the time of informed consent, no comorbidities in the acute stage, severe, decompensated, or unstable medical conditions, acute inflammatory diseases, or chronic inflammatory diseases in the acute stage at the time of screening, disability, organ surgery gastrointestinal tract).

Inclusion Criteria.

1. Male and female volunteers aged from 18 to 50 years old inclusive.
2. Body mass index (BMI) within 18.5–30.0 kg/m2 inclusive with body weight over 45 kg and not more than 100 kg inclusive.
3. Availability of a signed Form of Informed consent to participate in the study.

exclusion criteria.

1. The volunteer is currently participating in some other clinical study.
2. Volunteer taking medicines or dietary supplements containing vitamin D in the form of mono-preparations or combinations of vitamin D with calcium.
3. Clinical signs of malabsorption syndrome at the time of screening (eg 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 is investigation center, prevent the inclusion of a volunteer in the study.

The method of forming a sample from the studied populations

The recruitment of volunteers was carried out in the centers of INVITRO LLC, companies providing medical services to the population under the INVITRO® and INVITRO® trademarks on the basis of license agreements, sublicense agreements/commercial concession agreements, or involved by INVITRO LLC in the study, located in various regions of the country. us. Participants were enrolled consecutively for a limited period of time. The study was carried out according to a single protocol in all research centers.

Study Design

Russian multicenter non-interventional re gyrological study.

Primary end point: serum 25(OH)D level.

Secondary endpoint: demographic characteristics of study participants (age, gender, race).

Description of medical intervention

In this study, medical intervention patients were not treated.

Table 1. Distribution of study subjects by geographic regions

Geographic region	Men	Women	Total
Vladivostok	12	32	44
Yekaterinburg	11	31	42
Western Arctic	10	36	46
Red	14	31	45
Moscow	8	37	45
Novosibirsk	6	38	44
Norilsk	13	30	43
Rostov-on-Don	8	34	42
St. Petersburg	8	39	47
Tyumen	15	32	47
Total in study	105	340	445

Methods

Method for determining the level of 25(OH)D in blood serum. Blood analysis for 25(OH)D was performed by chemiluminescence immunoassay on microparticles at the centers of OOO INVITRO. According to the interpretation of the Russian Association of Endocrinologists in 2015, the level of 25(OH)D was regarded as adequate at ÿ30 ng/mL (ÿ75 nmol/L), deficiency — ÿ20 and <30 ng/mL (ÿ50 and < 75 nmol/l), deficiency - <20 ng/ml (<50 nmol/l), severe vitamin D deficiency - <10 ng/ml (<25 nmol/l). Reference interval of determination: 3.4–155.9 ng/ml.

Statistical analysis

The sample size was calculated to ensure sufficient accuracy in assessing the qualitative criteria. The analysis is stratified by region. Depending on the region, from 42 to 47 participants were included. 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 presented as medians (in Me format). When comparing two independent groups on a quantitative basis, the Mann–Whitney U test (U) was used to assess the statistical significance of intergroup differences. Communication Quantity

ing 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 ÿ² test. For statistical "weighting", we used up-to-date information on the population size depending on age and region, presented on the website of the Federal State Statistics Service ("Population of the Russian Federation by sex and age", url: https:// www.gks.ru/ compendium/document/13284 [accessed 07/09/2020]). The critical level of significance in testing statistical hypotheses was assumed to be 0.05.

Ethical review

This study was carried out strictly in accordance with the ethical principles proclaimed in the Declaration of Helsinki, ICH GCP (ICG CCP) 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 on Ethical Review of Clinical Research.

RESULTS

Objects (participants) of the study

The interim analysis of the results of the 1st stage of the study (spring 2020) included data from 445 subjects aged 18 to 50 from 10 regions of the Russian Federation. The largest number of volunteers was recruited in St. Petersburg and Tyumen (47 people each), the smallest - in Yekaterinburg and Rostov-on-Don (42 people each). Baseline characteristics of study participants by region are presented in Table 1.

Main results of the study

Prevalence of vitamin D deficiency and insufficiency in the study regions. According to the results of the study, the level of 25(OH)D deficiency was registered in 27.87% of volunteers, deficiency — in 56.40%. In total, 84.27% of the examined patients had a low vitamin D status, and the optimal level was diagnosed in 15.73%. Overall, the mean serum 25(OH)D level of participants was 20.87 ng/mL for the study (Table 2). When analyzing the primary endpoint in populations by geographic region, it was found that the percentage of subjects with vitamin D deficiency ranges from 29.55% (Vladivostok) to 82.22% (Kyzyl), with vitamin D insufficiency and deficiency - from 63.83 % (Tyumen) to 93.48% (Western Arctic). The results of the primary point assessment by geographic region are shown in Table 3.

demographic indicators. The next stage of this study was the analysis of the demographic status of the examined individuals. The study showed a strong association of low vitamin D levels with the age of the participants (p = 0.015, comparison of groups using a nonparametric test Mann-Whitney). The most pronounced vitamin D deficiency was found in young people in the age subgroup of 18–25 years (72.22%) (Fig. 1). In general, vitamin D deficiency and deficiency were found in 89.81% of subjects in this age subgroup. Taking into account the statistical "weighing" in the Russian Federation as a whole, 89.92% of young people

Table 2. Mean 25(OH)D levels (ng/mL) and prevalence of 25(OH)D deficiency and insufficiency, %

Geographic region	Prevalence of 25(OH)D deficiency and insufficiency, %	Average level of 25(OH)D, ng/ml
Vladivostok	75	26,77
Yekaterinburg	85,71	20,95
Western Arctic	93,48	19,96
Red	91,11	14,73
Moscow	86,67	18,69
Novosibirsk	81,82	22,27
Norilsk Rostov-	81,4	23,42
on-Don St. Petersburg	92,86	16,21
	91,49	19,8
Tyumen	63,83	25,74
Total in study	84,27	20,87

Table 3. Summary table of study results: serum total 25(OH)D levels, distribution by geographic region

I study period											
	Geographic region										
Serum total 25(OH)D	Vladivostok	Yekaterinburg	Western	Red	Moscow	Novosibirsk	Norilsk	Don	Petersburg Saint	Tyumen	Total
Deficit, %	29,55	61,90	50,00	82,22	60,00	54,55	51,16	73,81	61,70	40,43	56,40
Deficiency, %	45,45	23,81	43,48	8,89	26,67	27,27	30,23	19,05	29,79	23,40	27,87
Deficiency or insufficiency in total, %	75,00	85,71	93,48	91,11	86,67	81,82	81,40	92,86	91,49	63,83	84,27
Rate, %	25,00	14,29	6,52	8,89	13,33	18,18	18,60	7,14	8,51	36,17	15,73

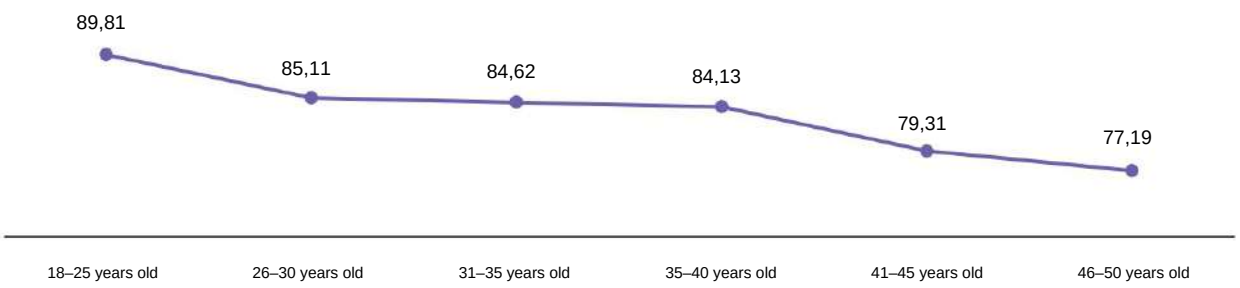

Figure 1. Dynamics of vitamin D deficiency and insufficiency depending on age, % (n= 445).

at the age of 18–25 years, they experience deficiency or deficiency of vitamin D. When assessing gender characteristics, a statistically significant predominance of deficiency and insufficiency of 25(OH)D in males compared to women (p=0.021, ÿ2 criterion Pearson) (Table 5, Fig. 2). Since the observed the distribution of study participants by gender (31:69) differs from the sex distribution of the population of the Russian Federation in the analyzed geographic regions, additionally, Table 4 shows the results of the main analysis of the study (estimating the proportion of participants with vitamin D deficiency and insufficiency)

Table 4. Summary table of study results after data “weighting”: total serum 25(OH)D levels, distribution by geographic region

	Study period I, serum 25(OH)D level											
Geographic region												
M:W ratio	48:52	46:54	47:53	48:52	46:54	47:53	47:53	46:54	47:53	48:52	46:54	
Deficit, %	30,00	61,47	50,00	82,14	58,92	53,83	50,52	73,05	61,20	40,10	55,96	
Insufficiency, %	45.00	23.67	43.31		8,76	27,39	27,70	30,49	19,60	30,37	23,49	28,05
Insufficiency or deficiency in total,%	75,00	85,14	93,31	90,89	86,31		81,53	81,01	92,65	91,57	63,59	84,01
Rate, %	25,00	14,86	6,69	9,11	13,69	18,47	18,99	7,35	8,43	36,41	15,99	

Table 5. Correlation of demographic indicators with the level of 25(OH)D

Pol		Having low levels of vitamin D	Absence low vitamin D	In general, according to the study
Female	Abs.	279	61	340
	%	74,40%	87,14%	76,40%
Male	Abs.	96	9	105
	%	25,60%	12,86%	23,60%
Differences between groups		Pearson 's ÿ2 test		0,021

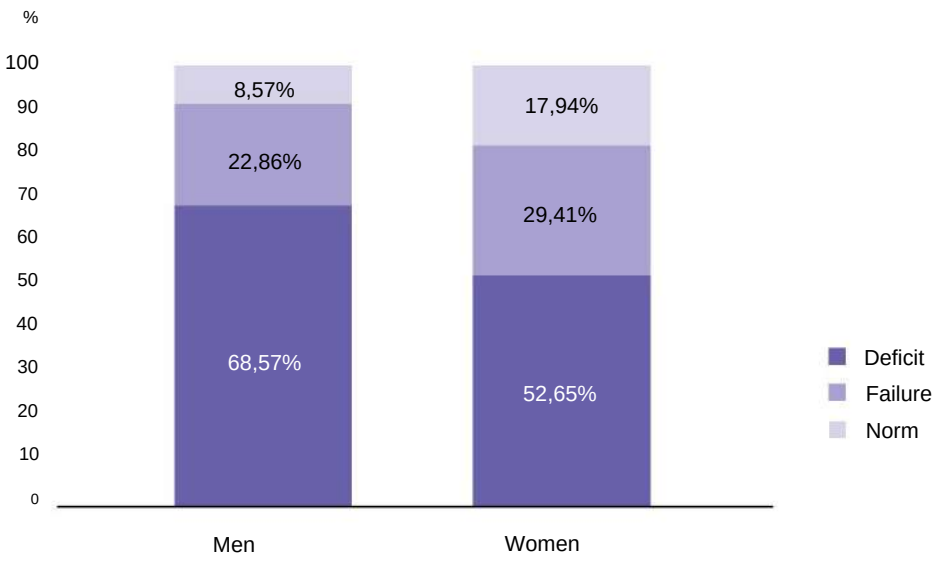

Figure 2. Vitamin D sufficiency by gender (n=445).

Table 6. Correlation of anthropometric parameters with the level of 25(OH)D

Indicators	N	Spearman R	t(N-2)	p	Availability correlations
Age	445	0,224	4,842	0,000	yes
Pol	445	0,161	3,429	0,001	yes
Race	436	-0,195	-4,148	0,000	yes

taking into account the statistical "weighting" of the data. Thus, taking into account the "weighting" of the data, in 55.96% of cases there is a deficiency of vitamin D, and in 84.01% - the level of its deficiency or insufficiency. Based on the results of the correlation analysis, it can be concluded that there is a statistically significant correlation between the age, sex, and race of the study participants with 25(OH)D in the blood serum. Table 6 shows a positive correlation of the 25(OH)D level with age (the older the participant, the higher the concentration); as well as gender and racial differences regarding 25(OH)D levels (in females, concentrations are on average higher than in males; in Caucasians, concentrations are higher than in Mongoloids).

Adverse events

No adverse events were recorded during the study.

DISCUSSION

Summary of the main result of the study

In the presented study, for the first time, a comprehensive assessment of the frequency of deficiency and insufficiency of vitamin D among residents living in different geographic latitudes of the country is given.

Discussion of the main result of the study

The results of various epidemiological studies that measured the levels of 25(OH)D in blood serum suggest that at present, at least 50% of the world's population has a low vitamin D supply [19–22]. The risk zone for vitamin D deficiency and insufficiency includes all residents living north of the 35th parallel, which corresponds to the entire territory of the Russian Federation, Kazakhstan, Mongolia, Turkey, Europe, as well as almost all of North America and China. Regions located at this geographic latitude receive insufficient UV radiation, especially in the autumn-winter months, which makes the synthesis of vitamin D from sunlight almost impossible [23]. In addition, numerous environmental factors, in particular the ever-increasing levels of air pollution due to dust and industrial waste, can reduce the impact of UV B radiation and thus prevent adequate vitamin D production [24, 25]. The extreme northern (near Cape Fligeli, Franz Josef Land, Arkhangelsk region 81 ° N), southern (a point not named on the maps with a height of more than 3500 m is located 2.2 km east of Mount Ragdan and southwest from the mountains Nesen (3.7 km) and Bazardyuzyu (7.3 km), Dagestan 41 ° N), eastern (Ratmanov Island, Chukot Autonomous Okrug 65°N) and western (frontier post Normeln, Baltic Spit, Kaliningrad Region 54°N) geographic points on the map of Russia fall into the belt of territories deficient in vitamin D. In this regard, in The Russian Federation has conducted a number of studies, the results of which are consistent with world data and confirm the widespread prevalence of low levels of vitamin D among all age groups of the country's population [18]. However, the data obtained on the epidemiological status of vitamin D deficiency and insufficiency in the Russian population cannot be considered unambiguous due to the diverse study population in terms of sex and age characteristics, chronic diseases and risk factors for low vitamin D status, as well as the study season. In addition, the lack of a unified protocol, inclusion/exclusion criteria, and standardized laboratory diagnostic methods in the conducted studies introduces discoordination in the interpretation and unification of the results obtained. Taken together, this determined the relevance of conducting an extensive epidemiological study covering regions that represent a geographically representative sample of regions of the Russian Federation with a high risk of developing an insufficient level of vitamin D.

The main criterion for assessing the primary final
The point of the study was to determine the percentage of participants with low levels of vitamin D, identified by measuring the level of 25(OH)D in the blood serum. In the study, the average level of 25(OH)D in the blood of study participants was 20.87 ng/ml, which corresponds to the level of vitamin D deficiency, while being close to the border with D-deficiency. At the same time, in half of the studied territories (Moscow, St. Petersburg, Rostov-on-Don, Western Arctic, Kyzyl), the level of 25(OH)D corresponded to values below 20 ng/mL, which indicates in favor of a rather wide prevalence of its deficiency. It is also worth noting the regions with the lowest low values of 25(OH)D - these are the cities of Tyumen (25.74 ng/ml) and Vladivostok (26.77 ng/ml). The data obtained are also consistent with the data on the overall prevalence of vitamin D deficiency and insufficiency and are in the range of 63.83–93.48%, where the highest rates were registered in the Western Arctic (93.48%) and Rostov-on-Don (92.86%), and the smallest - in Tyumen (63.83%) and Vladivostok (75%). Attempts to estimate the prevalence of vitamin D deficiency and insufficiency have already been made in various populations in individual regions of the country. So, for example, among visitors to a polyclinic in the Moscow region, an assessment was carried out in a study in which

included 565 patients (373 women, 192 men). According to its results, the optimal concentration of vitamin D was found in 38% of patients (n=213); (39.7±9.6 ng/ml), vitamin D deficiency — in 25% (n=141); (16.2±3.4 ng/ml), and insufficiency — in 37% (n=211); (24.9±2.5 ng/ml). Thus, 62% of patients have a low level of vitamin D [26], which is 24.67% lower than the data obtained in Moscow in this study (86.67%). When analyzing the published material of researchers from the northwestern region of the Russian Federation, where the level of vitamin D sufficiency was studied among 1569 residents of St. Petersburg and Petrozavodsk, it was noted that indicators of vitamin D deficiency and deficiency are extremely common - in .2% [27] of cases, which is practically comparable to the study, where this figure reached 91.49%. At the same time, the study of the content of 25(OH)D in the blood serum of 5335 patients in Rostov-on-Don showed that vitamin D deficiency was found in 2314 (43.3%), the level of 25(OH)D deficiency was in 2066 (38.8%) patients, while the optimal values were in 943 (17.6%) patients. In total, inadequately low vitamin D status relative to standard values was detected in 82.1% of the examined [28], while in the present study it was 92.86%. Also, a high frequency of low vitamin D levels was confirmed among the adult population living in the Tyumen region (n=440). According to the results, deficiency was registered in 22.0% of cases, and deficiency in 70.7% [29] compared with 63.83% in the present study.

Baseline demographic characteristics such as gender, age, and race were used as the basis for assessing the secondary endpoint. The present study noted a higher incidence of vitamin D deficiency in males, as well as in a subgroup of young people aged 18 to 25 years. It should be noted that the results obtained do not correlate with published literature data [8, 29], which do not contain statistically significant data on the relationship between 25(OH)D and the sex or age characteristics of the examined individuals. Nevertheless, the information obtained may indicate “hidden alimentary hunger for vitamin D” due to the altered high-calorie, but micronutrient-deficient nature of the diet. The resulting correlation of 25(OH)D levels with the Mongoloid race can be characterized in terms of dark skin color, which may require 3–5 times longer exposure to sunlight to produce the same amount of vitamin D compared to fair-skinned people [30]. In addition, anthropometric characteristics, lifestyle, eating habits, clinical symptoms, consumption of medical resources (number of days of incapacity for work, number of visits to general practitioners and specialists per year, number of hospitalizations), as well as the use of medications and the presence of certain chronic diseases are considered as significant risk factors for the development of D-deficiency, which requires additional analysis and evaluation in the study population. Taken together, all these data determine the prospects for further study of the prevalence of vitamin D deficiency and insufficiency in the Russian Federation.

Summarizing the totality of the results obtained and published literature data, the problem of vitamin D deficiency can be classified as a pandemic that is typical for all regions of the country. That is why the study of the prevalence of vitamin D sufficiency does not lose its relevance and becomes of paramount importance for addressing the issues of timely prevention, early diagnosis and adequate treatment of low vitamin D status, which are identified as key reasons necessary to improve health and improve the quality of life of the population [31].

Direction for further research

Further study of the problem of vitamin D deficiency and insufficiency in Russia is to conduct a second autumn-winter wave to analyze the totality of the results obtained throughout the calendar year, as well as to assess risk factors for developing low vitamin D status.

CONCLUSION

Beginning of the 21st century can be marked by the second era of vitamin D deficiency, after the victory over rickets in the middle of the 20th century. The high prevalence of low vitamin D sufficiency in the territory of the Russian Federation justifies the need to study the risk factors for the development of D-deficient conditions, and also dictates the importance of further study of the epidemiological status. To correct vitamin D deficiency, there is a fairly wide range of drugs containing cocalciferol, but most of those registered on the domestic market are dietary supplements, while only the drug has registered indications for the treatment of vitamin D deficiency and deficiency. Since vitamin D is a fat-soluble vitamin, the main mechanism of its absorption in the gastrointestinal tract, like other fat-soluble vitamins, is micellation. The use of a drug based on a micellar solution of colecal ciferol (Aquadetrim®) ensures a good degree of absorption, regardless of the composition of food, medication or the state of the gastrointestinal tract. Aquadetrim® dissolvable tablets are a convenient form of vitamin D that can be dissolved either in the mouth or in a small amount of water. The expansion of the geography of vitamin D deficiency in the Russian Federation in the aggregate will contribute to the creation and development of educational and preventive programs, which may be reflected in the National Clinical Guidelines.

ADDITIONAL INFORMATION

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Conflict of interests. The authors declare the absence of obvious and potential conflicts of interest related to the publication of this article.

Author participation. Suplotova L.A. — editing the relevance and the main text of the manuscript; Avdeeva V.A. — writing the main text of the manuscript; Rozhinskaya L.Ya., Pigarova E.A., Troshina E.A. — editing the main text of the manuscript. All authors approved the final version of the article before publication, agreed to be responsible for all aspects of the work, which implies proper study and resolution of issues related to the accuracy or integrity of any part of the work.

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