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CLINICAL AND LABORATORY EFFICACY AND SAFETY OF THE USEOF THE DRUG ANTIBACTERIAL EAR DROP IN CHILDREN IN THE TREATMENTOF ACUTE PURULENT OTITIS MEDIA

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✓ ***Resume***

The study of the clinical and laboratory eff ectiveness of the use of the drug antibacterial ear drop in the complex treatment of children with acute middle purulent otitis (AMPO) was made. Under supervision were 42 children with AMPO, who were randomized into 2 groups. Patients of the control group (20 children) took conventional therapy for AMPO, and the main group (22 children) named after additional local treatment with Antibacterial ear drop. All patients underwent a clinical and laboratory examination, as well as bacteriological examination for microflora and antibiotic sensitivity before and after treatment. According to the results of the study, the clinical symptoms regressed 2 times faster: earache and purulent discharge (p<0.05), and the frequency of patients with pathogenic microorganisms, except for Klebsiela pneumoniae, also decreased reliably. Antibacterial ear drop is a safe

and eff ective drug when used in childhood as part of the complex therapy of OSGO.

Keywords: acute purulent otitis media, children, treatment.

КЛИНИКО-ЛАБОРАТОРНАЯ ЭФФЕКТИВНОСТЬ И БЕЗОПАСНОСТЬ ПРИМЕНЕНИЯ ПРЕПАРАТА АНТИБАКТЕРИАЛЬНОГО УШНОГО КАПЛЯ У ДЕТЕЙ ПРИ ЛЕЧЕНИИ ОСТРОГО СРЕДНЕГО ГНОЙНОГО ОТИТА

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✓ ***Резюме***

Произведено изучение клинико-лабораторной эффективности использования препарата Антибактериального ушного капля в комплексном лечении детей с острым средним гнойным отитом (ОСГО). Под наблюдением находились 42 ребенка с ОСГО, которые были рандомизированы на 2 группы. Пациенты контрольной группы (20 детей) принимали общепринятую терапию ОСГО, а основная группа (22 ребенка) получала дополнительно местное лечение с Антибактериального ушного капля. Всем пациентам проводилось клинико-лабораторное обследование, а также бактериологическое исследование на микрофлору и чувствительность к антибиотикам до и после лечения. По результатам исследования у пациентов основной группы в 2 раза быстрее регрессировали клинические симптомы: боль в ухе и наличие гнойных выделений (p<0,05), а также достоверно снизилась частота выявления патогенных микроорганизмов, за исключением Klebsielapneumoniae. Антибактериального ушного капля является безопасным и эффективным препаратом при местном использовании в детском возрасте в составе комплексной терапии ОСГО.

Ключевые слова: острый средний гнойный отит, дети, лечение, Антибактериального ушного капля.

BOLALARDA O'TKIR YIRINGLIOTITNI DAVOLASHDA ANTIBAKTERIAL QULOQ TOMCHISI DORI VOSITALARINING KLINIK VA LABORATOR SAMARADORLIGI VA FOYDALANISHNING XAVFSIZLIGI

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✓ ***Rezyume***

Antibakterial quloq tomchisidan foydalanishning klinik va laboratoriya ta'sirini o'rganish.

O'tkir yiringli o'rta otit (O`YO`O) bo'lgan bolalarni kompleks davo lashamalga oshirildi. Kuzatuv ostida 42 nafar bola edi, ular O`YO`O bilan birga 2 guruhga bo`lib o`rganildi. Nazoratchi bemorlar guruhi (20 bola) O`YO`O uchun an'anaviy terapiya va asosiy guruh (22 bolalar) antibacterial quloq tomchisi bilan qo'shimcha mahalliy davolanishdan keyin. Barcha bemorlar klinik va laboratoriyaga ega bo'lishdi ekspertiza, shuningdek oldin mikroflora va antibiotiksezgirligi uchun bakteriologik tekshirish va davolanishdan keyin. Tadqiqot natijalariga ko'ra klinik alomatlar 2 marta regressga kirdi tezroq: Quloq va yiringli oqindi (p <0,05) va pathogen kasal bo'lgan bemorlarning chastotasi Klebiella Pnummoniya dan tashqari mikroorganizmlar ham qat'iy kamaydi. Antibakterial quloq tomchisi- bu xavfsiz.

Bolaligida OSG anikompleks davolashning bir qismi sifatida ishlatilganda imtiyozli dori.

Kalitso'zlar: o'tkiryiringlio`rtaotit,bolalar,davolash.

Relevance

Acute otitis media (OSA) is one of the most common diseases of childhood. The incidence of otitis media remains stably high. Thus, in 2005 it was 23.96 per 1,000 children, in 2013 it was 27.21. - 27.21, in 2014. - 25.82, in 2015. - 25,36 [2,15]. It has been found that up to 60% of children under the age of 1 year have a single episode of CCA, and up to 20% have 2-3 or more episodes of the disease. According to studies conducted in the United States, during the first 3 years of life, up to 90% of children suffer from CCA at least once. Transmitted in childhood otitis media in 25.5% of cases causes the development of hearing loss in older children and adults [6,18]. It has been established that the pathogenesis of OSA is based on the dysfunction of the auditory tube and its permeability or functional changes associated with the ineffectiveness of its physiological activity mechanism. Both mechanisms lead to the creation of negative pressure in the tympanic cavity and fluid transudation, which is initially sterile, but becomes inflammatory after the ingress of bacterial or other flora [5,16]. Treatment tactics in this case is aimed at the elimination of the pathogen, regeneration of damaged tissues and restoration of the functional structures of the middle ear. Systemic antibacterial therapy for such conditions is primarily required in the empirical treatment of patients with otitis media with ear pain and pronounced temperature reaction (development of acute purulent inflammation), which is mainly observed in children under 2 years of age [8,10,17].Treatment of patients with purulent otitis media is a complex of adequate local and general therapeutic measures. In addition to the mandatory sanation of the upper airways (UARS), especially the nasal pharynx, significant attention should be paid to the adequate selection of local medications [1, 7].

These drugs should have a number of pharmacological properties: anti-inflammatory, antibacterial, antifungal action, have a pronounced analgesic effect [9]. At the same time, topical preparations should also have a broad antimicrobial spectrum of action, low toxicity, ease of use, and an optimal price-to-quality ratio. The basic etiopathogenetic principle for the treatment of patients with acute otitis media (OSOM) is antimicrobial therapy, both topical and systemic. The choice of a drug should take into account the epidemiological situation, the clinical symptomatology and severity of the disease, the age of the patient, the presence of concomitant diseases, the history of previous antibiotic therapy and drug tolerance. Antibiotics should be prescribed on strict indications, their antimicrobial spectrum should be adequate, and the dosages and duration of treatment should be optimal.

Local antibacterial and anti-inflammatory treatment is therefore of great importance to avoid systemic drug metabolism and to ensure that the optimal dose of active substance is delivered directly to the lesion. Local antimicrobial therapy is primarily indicated for the combined course of external diffuse otitis media and OSHA [4].

Most drugs used in otorhinolaryngology to combat inflammatory processes in the ear have certain restrictions on their use. They are either focused on fighting fungal flora, or they act on certain types of bacteria. Most researchers tend to believe that inflammatory processes in the ear are often provoked first by viral agents, and then by bacterial and bacterial-fungal associations [3]. This aspect allows us to count on the high therapeutic effectiveness of topical preparations with an extended spectrum of antimicrobial and antifungal activity. The safety of the components that make up the ear drops is of great importance in local therapy, especially in children. In this regard, the drug Antibacterial ear drop (Farmak,Ukraine) deserves attention - a combined local medication, which includes in its composition: active ingredients: ciprofloxacin; dexamethasone; 1 ml of the drug contains ciprofloxacin

hydrochloride 3.5 mg converted to 100% ciprofloxacin anhydrous substance, 3.0 mg dexamethasone converted to 100% dry substance 1.0 mg; excipients: hydroxyethylcellulose; benzalkonium chloride, sodium acetate, trihydrate; glacial acetic acid; sodium chloride, edetate disodium; tiloxapol; boric acid; water for injection; sodium hydroxide solution or diluted hydrochloric acid. This composition of Antibacterial ear drop makes it highly effective against inflammatory processes in both the external and the middle ear of patients. Ciprofloxacin contained in Antibacterial ear drop has a broad spectrum of activity [11] and has a dual mechanism of action (destroys not only the bacterial genome.

Purpose of the study: To evaluate the efficacy and safety of local therapy in children in the treatment of acute suppurative otitis media with the use of Antibacterial ear drop.

Materials and methods

For the period of 2021 in Bukhara Regional children's clinical hospital ENT department, which is the base of Otorhinolaryngology Department, the clinical-laboratory study of efficacy of TsiprofarmDex in complex treatment of children with acute media purulent otitis was carried out.

For this study and dynamic monitoring of patients, 42 children with otitis media were examined. The age range of the examined children was from 6 months to 18 years.The inclusion criteria for the study were boys and girls with OSH, aged from 6 months to 18 years, who were diagnosed with mild to moderate OSH, patient consent to participate in the study and comply with its requirements.

Patients were divided into two clinical groups depending on the therapeutic tactics chosen. In the main group (n=22) patients received conventional therapy (standard indications - antibiotics, nonsteroidal anti-inflammatory drugs), and, in addition, topically in the affected ear 3-4 drops of Antibacterial ear drop 3-4 times a day for 7 days. The control group (n=20) received conventional therapy without topical drops of Antibacterial ear drop in the affected ear.

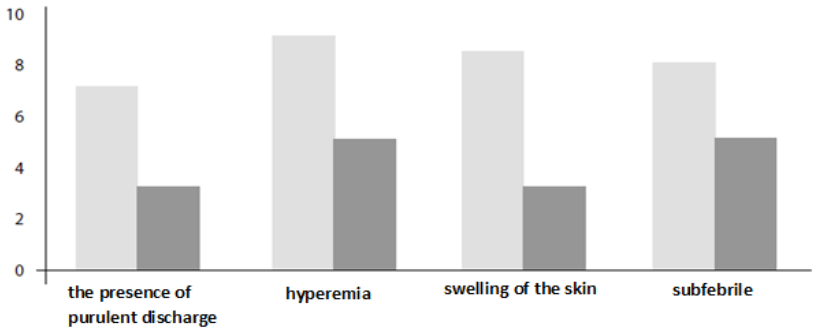
Patients in both clinical groups underwent general clinical examination according to local protocols, as well as bacteriological examination for microflora and sensitivity to antibiotics of purulent discharge from the ear and external auditory canal in the presence of diffuse inflammation.

Results and discussion

The general condition of the patients of both groups, who were involved in the clinical study, was predominantly of moderate severity. Before treatment, the children's complaints were ear pain, chills, weakness, and purulent discharge from the ear. The clinical signs at micro-otoscopy in children with OSGO were hyperemia and swelling of the skin of the external auditory canal, hyperemia and thickening of the tympanic membrane (b/p), the presence of purulent discharge in the ear at tympanic membrane perforation, subfebrile. These indicators were evaluated in the dynamics of treatment in children of both observation groups.

According to the results of the course of the complex treatment a significant difference in the duration of complaints was found between the patients who received the standard therapy and those who received locally the drug Antibacterial ear drop.

As can be seen from Fig. 1, patients in the main group regressed twice as quickly to the following clinical symptoms: ear pain, presence of purulent discharges ($p<0.05$). When standard baseline therapy was used, subjective complaints remained in almost half of the patients until the 6th-7th day of treatment.



duration of symptoms in children with OSHO of the main group

It should be noted that against the background of topical administration of Antibacterial ear drop in children with OSHO in none of the cases pronounced allergic reactions were observed. Clinical observation of the patients of both groups in the course of treatment revealed that objective changes in the NRS and tympanic membrane also significantly faster regressed in the children of the main group, they also retained subfebrile symptoms and the presence of purulent discharge in the ear for less time ($p<0.05$), which is reflected in Table 1. The bacteriological studies conducted in children with OSHO determined the characteristic features of the state of the NRS microbiocenosis, which was characterized by the fact that pathogenic microorganisms were practically not isolated as monocultures. The detected combined pathogenic microflora in children with OSGO indicated a significant violation of the state of colonization resistance in these patients.

The results of bacteriological examination in children with OSGO in the main and control groups are shown in Table 2. As can be seen from Table 2, there was no significant difference in the frequency of detection of bacteria and fungi in both observation groups ($p>0.05$).

Table 1

Duration of CTP symptoms in children of both observation groups

clinical symptoms	control group (n=20)	main group (n=22)
purulent discharge in the ear	7,2±0,6	3,2±0,4*
hyperemia	9,3±0,4	5,1±0,3
swelling of the skin	8,6±0,5	3,3±0,5*
subfebrility	8,1±1,1	5,2±0,6

note:the reliability of the difference compared to the indicators of the control group

Table 2

Microflora in children with CTP of the main and control groups before treatment %

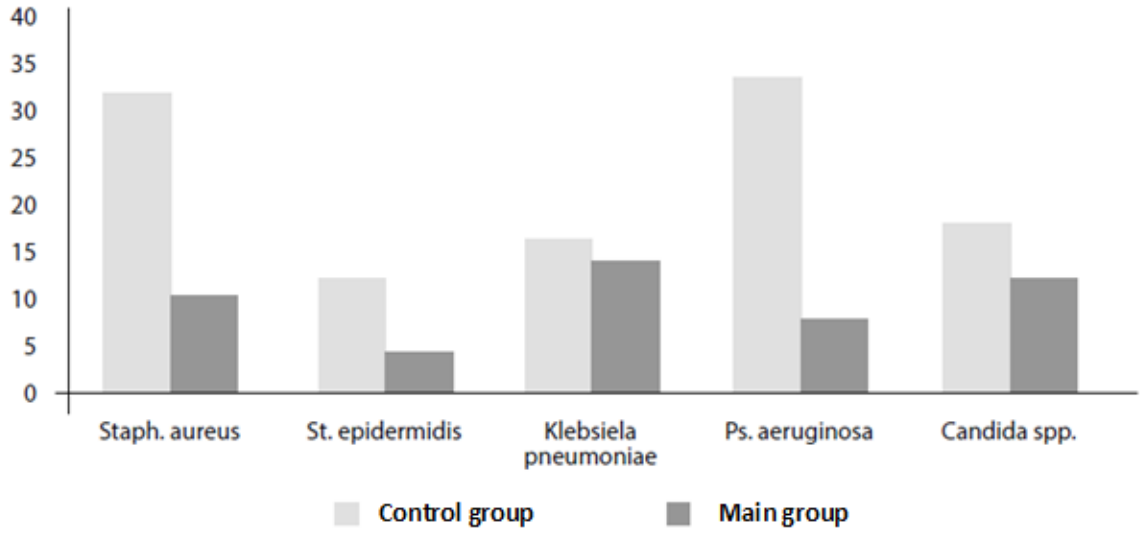
Microflora in children with CTP	control groups	main groups
Staph. aureus	62	58
St. epidermidis	48	40
Klebsiela pneumoniae	28	22
Ps. aeruginosa	42	48
Candida spp.	36	38

According to the results of the observation within 10 days after the complex treatment in patients of the control group who received standard treatment, there were no significant changes in the NRS microbiocenosis, except for a significant increase in the frequency of Candida fungi detection ($p<0.05$). There was a clear trend towards a decrease in the colonization frequency of Staph. aureus, Ps. aeruginosa, St. epidermidis, since antibacterial agents are mainly selected taking into account the antibiotic sensitivity of the dominant strain of the pathogenic microorganism.

The use of complex treatment in the main group patients contributed to a significant improvement of the NRS microbiocenosis, and this concerned not only bacteria (Staph. aureus, Ps. aeruginosa), but also Candida fungi (Fig. 2).

As evidenced by the results of the study of the NRS microbiocenosis in children of both observation groups, presented in Table 3, the frequency of detection of almost all pathogenic microorganisms ($p<0.05$), except for Klebsiela pneumoniae, was significantly reduced in patients of the main group.

Evaluating the results of the clinical observation, we can note that the leading complaint of patients with OSGO was pain syndrome (96%), worsening of hearing and itching in the ear were disturbed by approximately the same ear discharges. Ear pain varied in different forms of OSG, but in all cases, topical application of Antibacterial ear drop drops accelerated the period of regression of clinical symptoms of the disease by 2 times.The following are some of the most important findings of the



Pic. 2

Microflora in children with CTP of the main and control groups after treatment, %

Tabl. 3

Microflora in children with CTP of the main and control groups after treatment, %

Microflora	control group (n=20)	main group (n=22)
Staph. aureus	32	10*.**
St. epidermidis	12	4*.**
Klebsiela pneumoniae	16	14
Ps.aeruginosa	34	8*.**
Candida spp.	18**	12*.**

Note

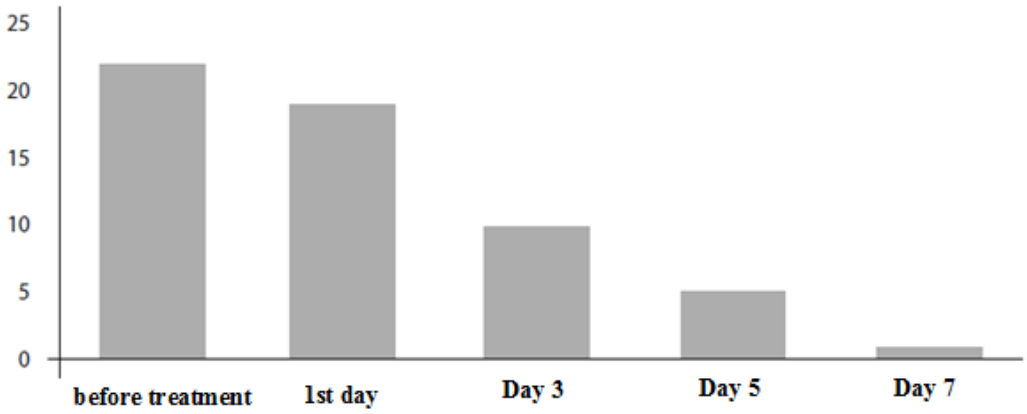
The reliability of the difference compared to the indicators of the 1st group

The significance of the difference compared to the indicators before treatment

Thus, one day later, 62% of the patients in the main observation group reported a decrease in pain. This symptom progressively decreased, and by the 3rd day, only 14% of patients reported ear pain, and up to the 5th day, 2% did so (Fig. 3).

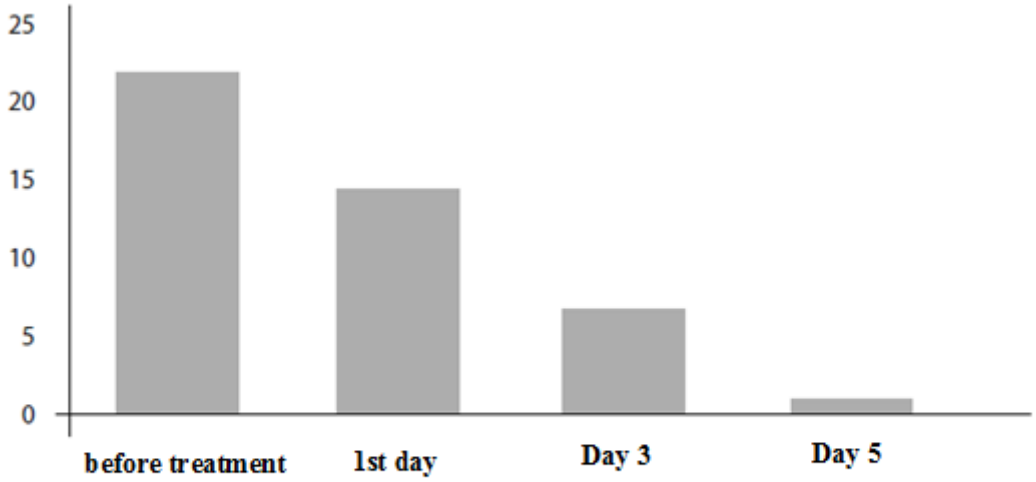
Observation and analysis of clinical data of patients with OSGO in the main group showed that already after 24 hours the discharge from the affected ear significantly decreased in 14% of patients, after 3 days - in 60%, after 5 days - in almost 90%. However, in the control group of observation such rapid dynamics of regression reduction in the duration of discharge from the ear was not observed.

Thus, the effect of Antibacterial ear drop was the highest when assessing the amount of discharge from the ear. Ear itching is also one of the leading symptoms of the course of external otitis media, especially of fungal etiology. Application of the multi-component preparation Antibacterial ear drop in children of the main observation group resulted in a rapid reduction of ear itching - after 24 hours in 34%, on the 3rd day - in 70% and up to the 5th day only 5% of patients had remaining ear itching. The sedata are reflectedin Fig. 4.



Pic. 3

The time of onset of the effect in children of the main group



Pic. 4

The time of onset of the effect (ear itching) in children of the main group

It should be noted that hearing function in patients with various forms of NRS and middle ear inflammation is affected by many factors, but all of them mainly lead to the development, as a rule, of conductive hearing loss. In the clinical follow-up of children with OSHA, hearing recovery was somewhat slower than in the discharge assessment, but there was a significant trend toward more rapid hearing function recovery in children in the main group. It should be noted that ciprofloxacin, which is included in Antibacterial ear drop, has no ototoxic effect and can be prescribed from 6 months of age [14].

Regarding the tolerability of the drug, it was evaluated independently by the patient at each visit. Tolerability criteria were as follows: very good - no adverse events during therapy with the study drug and during follow-up; satisfactory - mild transient side effects that did not require cancellation of the study drug; poor - moderate or severe side effects that required cancellation of the study drug or prescription of additional examination methods and corrective therapy.

More than 82% of patients reported tolerability as very good. In addition, none of the examined and treated children with OSG with topical use of Antibacterial ear drop was found to have chronicity of the process, transition of inflammation to the bone part of the mastoid process, the labyrinth or the facial nerve, or development of intracranial complications.

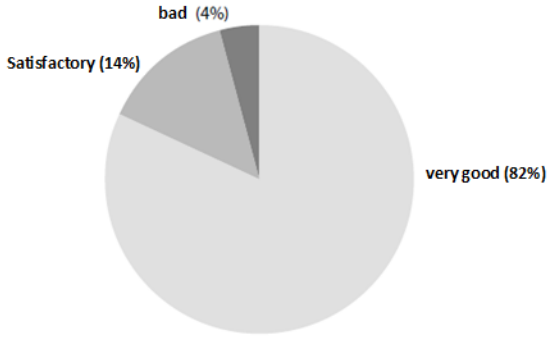


Fig.5. assessment of tolerability of an antibacterial ear drop in patients with OSHO

Conclusions

Antibacterial ear drop produced by "Farmak" (Ukraine) in treatment of children with OSGO has very good tolerability and high therapeutic activity, does not cause local and general pathological changes in the body that is confirmed by the clinical and laboratory examination of patients.

Antibacterial ear drop is safe and effective when administered locally in children as part of the complex therapy of OSHO, which reduces the course of the disease by half, as well as quickly and safely reduce the manifestations of inflammation in the external auditory canal and middle ear cavity. Topical use of "Antibacterial ear drop" in the treatment of OSHO in children at its early diagnosis makes it possible to avoid invasive methods of treatment in children not only by reducing symptoms, but also providing pathogenetic therapeutic effect, which is due to the content of anti-inflammatory components in its composition, in particular - dexamethasone.

TsiprofarmDex can be recommended for wide use in otorhinolaryngology in the treatment of patients with inflammatory processes in the external auditory canal, as well as for pus from the ear in perforative stages of OSHA.

LIST OF REFERENCES:

1. 1.Afonkin V.Y. Hearing rehabilitation in patients with acute otitis media on the background of fenspiride application V.Y. // Vestn. otorhinolaring. - 2018.- № 1 - C. 59-60.
2. Bessarab TP Yushchuk ND "HIV-infection in otorhinolaryngological practice. - Lech. vr. - 2014. - № 1. - C.26-28.
3. 3.Balyasinskaya G.L.Ear drops Otofa and Polideksa in the treatment of children with acute middle and external otitis media. //Vestn. otorhinolaring. - 2013. - № 3. - C. 53-54.
4. Bogomilsky MR The place of macrolides in antibacterial therapy of otitis media in children. //Vestn. otorhinolaring. - 2017. - № 2. - C. 34-36.
5. Bogomilsky MR, Palunin MM, Polyakov DP et al. The state of hearing in children who underwent acute media otitis media with the use of paracentesis. (in Russian) //Vestn. Otorhinolaring. - 2008. - № 1. - C 17-20.
6. VokhidovN.Kh. Interpretation of leukogram in acute purulent media otitis media in infants // Vestn. otorhinolaring. - 2002. - № 6. -C 48-49.
7. Garashchenko T.I., Desinova O.A., Kotov R.V. Start antibiotic therapy for acute middle otitis and acute sinusitis in children. //Vestnotorhinolaring. - 2015. - № 3. - C 62-63.
8. Garaschenko T.I., Bogomilsky M.R. Modern problems of physiology and pathology of hearing. // Mater. The Second International Symposium: Theses of reports, M: 1995. - C. 20.
9. Narzullayev N.U. State of the immune status in HIV-infected children with acute rhinosinusitis // Journal of Dentistry and Craniofacial Research.2022.Samarkand.Special Issue.-P.232-235.
10. Narzullaev N.U. Effectiveness of the use of Silver Plus in the complex treatment of HIV-infected children with acute purulent rhinosinusitis // Journal of Dentistry and Craniofacial Research.2022.Samarkand.Special Issue.-P.245-247.
11. Narzullaev N.U. Results of complex differential treatment of allergic rhinitis in school-aged children// Journal of Dentistry and Craniofacial Research.2022.Samarkand.Special Issue.-P.239-241.
12. Narzullaev.N.U. Muscovites in the structure of opportunist of middle ear infections in hiv-infected children// Middle-European scientific bulletin.2022.-P.211-212.
13. Narzullaev.N.U. Characterization of cytokines in hiv-infected children children with acute rhinosinusitis// Evrasian Scientific Herald.Vol.5.2022.-P.127-129

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