

# Minimal essential text

(Key findings + graphics)

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## Safety of Combination of a Tetravalent Meningococcal Conjugate Vaccine Against Serogroups A, C, Y, W-135 With Other Vaccine Preparations: a Prospective Study of a Series of Cases Among Healthy Children and Children With Various Health Abnormalities

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**Background.** Meningococcal infection is an acute disease caused by *Neisseria meningitidis*, which proceeds with a diverse clinical aspect from nasopharyngitis to meningococcal meningitis and meningococemia. Since 2014, a tetravalent meningococcal conjugate vaccine has been registered in Russia. This vaccine creates protection against serogroups A, C, W-135, Y and can be used from the age of nine months to 55 years. The actual issue is a vaccine tolerability, including when combined with other vaccine preparations. **Objective:** Our aim was to evaluate the safety of a tetravalent meningococcal conjugate vaccine against serogroups A, C, Y and W-135 when it is combined with other vaccine preparations. **Methods.** A prospective full-design study assessed the tolerability of immunization with a meningococcal conjugate vaccine, both in case of monovaccination and in combination with a pneumococcal 13-valent conjugate vaccine, measles-mumps-rubella, viral hepatitis A, influenza, and chicken pox vaccines. **Results.** 97 children aged from 9 months to 18 years were vaccinated, 20 of them were healthy and 77 had medical issues (with allergic pathology, ENT diseases, cardiovascular and nervous system diseases, lung diseases as well as orphan diseases). Among vaccinated children, general reactions were observed in 3/97 (3.1%) children, local reactions — in 5 (5.2%). The post-vaccination period passed asymptotically and uneventfully in the prevailing majority of children vaccinated with a tetravalent meningococcal conjugate vaccine (in 91, 93.8%).

**Conclusion.** The immunization with a tetravalent meningococcal conjugate vaccine against serogroups A, C, Y, W-135 is well tolerated, both in case of monovaccination and in combination with other vaccine preparations, in healthy children of different age groups and in patients with different health status.

**Key words:** children, meningococcal infection, vaccination, tetravalent meningococcal conjugate vaccine, tolerability of vaccination.

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## RESULTS

**Table 1.** The intensity of local reactions

Intensity	Sign symptoms (hyperemia, edema); diameter, cm	Subjective sensation (pain, burning, discomfort)	Duration of a local reaction, days
Low	≤ 5	Minor	≤ 3
Strong	> 5	Pronounced	> 3

**Table 2.** The intensity of a general reaction to vaccination

Intensity	Body temperature, °C	Weakness, headache	Duration of a general reaction, days
Low	37.0-37.9	Minor	≤ 2
Strong	≥ 38.0	Pronounced	> 2

**Table 3.** The frequency of local and general post-vaccination reactions depending on the age of patients

Age	Local reactions, abs. (%)	General reactions, abs. (%)
< 1 year ( <i>n</i> = 12)	-	-
1 year – 1 year 11 months ( <i>n</i> = 31)	1 (3)	-
2 years – 10 years 11 months ( <i>n</i> = 30)	3 (10)	2 (7)
≥ 11 years ( <i>n</i> = 24)	1 (4)	1 (4)

**Table 4.** The frequency of local and general post-vaccination reactions in healthy children and in children with medical issues

Health status	Local reactions, abs. (%)	General reactions, abs. (%)
Healthy ( <i>n</i> = 20)	3 (15)	1 (5)
Allergic diseases ( <i>n</i> = 32)	1 (3)	1 (3)
ENT diseases ( <i>n</i> = 15)	-	-
Delay in speech development ( <i>n</i> = 10)	-	-
Severe disabling diseases ( <i>n</i> = 20)	1 (5)	1 (5)

**Table 5.** The frequency of post-vaccination reactions depending on combination of vaccine preparations

Vaccination	Local reactions, abs. (%)	General reactions, abs. (%)
Monovalent immunization ( <i>n</i> = 15)	2 (13)	2 (13)
Combined vaccination ( <i>n</i> = 82)		
• Pneumococcal infection ( <i>n</i> = 23)	1 (4)	1 (4)
• Measles, rubella, parotitis ( <i>n</i> = 3)	-	-

• Viral hepatitis A ( <i>n</i> = 15)	-	-
• Chicken pox ( <i>n</i> = 23)	2 (9)	-
• Influenza ( <i>n</i> = 6)	-	-
• Viral hepatitis A and chicken pox ( <i>n</i> = 6)	-	-
• Measles-rubella-parotitis and chicken pox ( <i>n</i> = 3)	-	-
• Influenza and chicken pox ( <i>n</i> = 2)	-	-
• Influenza and pneumococcal infection ( <i>n</i> = 1)	-	-

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