

Multivitamin Supplements for delaying HIV Disease Progression and Mortality

CITATION

Fawzi W W et al. A Randomized Trial of Multivitamin Supplements and HIV Disease Progression and Mortality. *N Engl J Med* 2004;351:23-32

RESEARCH QUESTION

Does multivitamin supplements delay the progression of HIV disease and mortality?

THE STUDY DESIGN

Randomized double blind placebo controlled trial

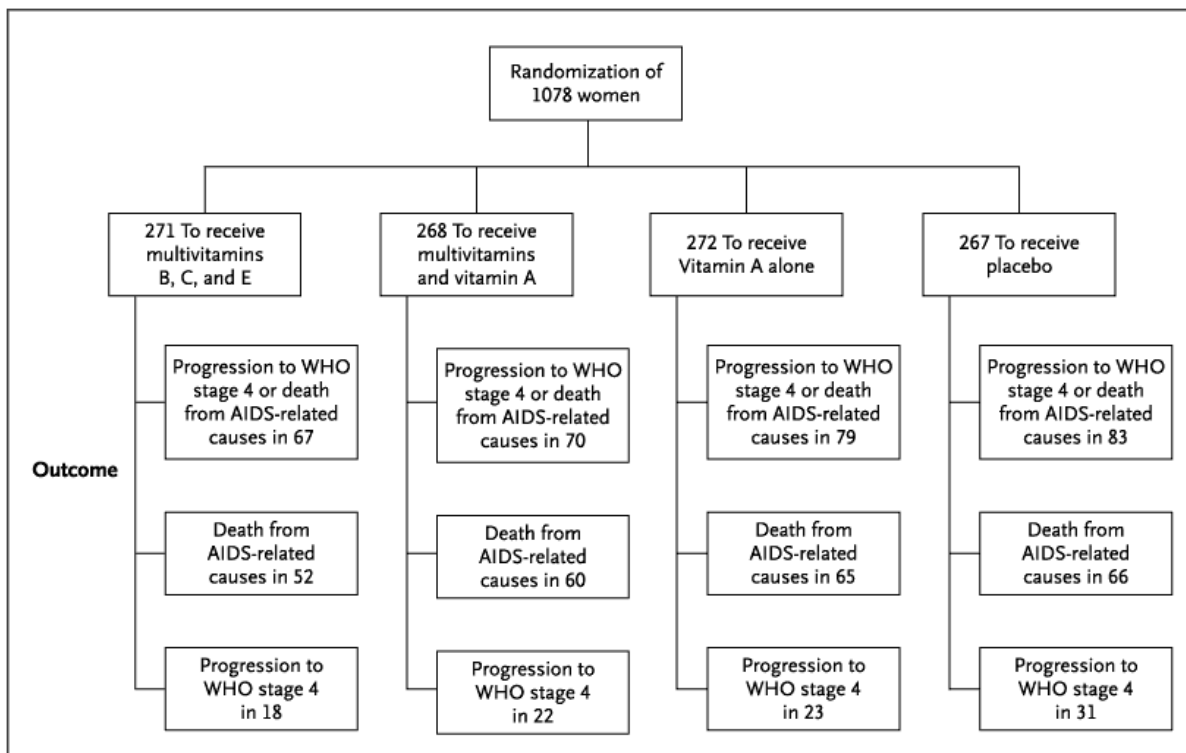
STUDY SETTING

Dar es Salaam, Tanzania
April 1995 – August 2003

PARTICIPANTS

Included: HIV-infected pregnant women
Excluded: No mention of it was made

INTERVENTIONS & OUTCOMES



Supplementary Appendix available at www.nejm.org

Interventions

All women received standard doses of antenatal folic acid and iron.

Multivitamins: 20 mg of vitamin B₁, 20 mg of vitamin B₂, 25 mg of vitamin B₆, 100 mg of niacin, 50 µg of vitamin B₁₂, 500 mg of vitamin C, 30 mg of vitamin E, and 0.8 mg of folic acid.

Vitamin A: 30 mg of beta-carotene plus 5000 IU of preformed vitamin A

Multivitamins & vitamin A: Same doses listed above

Control: Placebo

Received a daily oral dose of one of the four regimens for the duration of the follow-up

Outcomes

Clinical disease progression, HIV-related complications, CD4+ cell counts, Viral load

RISK OF BIAS (Risk Scale: Low – Moderate – High)

SELECTION BIAS: Low – Moderate

HIV-infected pregnant women were randomly assigned in blocks of 20. Allocation concealment not reported.

PERFORMANCE BIAS: Low

(I.e what else happened that may have affected the result?)

All women received standard doses of antenatal folic acid and iron. Placebo controlled trial. All clinical and follow-up staff were unaware of the women’s treatment assignments.

DETECTION BIAS: Moderate

All clinical and follow-up staff were unaware of the women’s treatment assignments.

Monthly visits. Physical examination. Health history of the women for the preceding period.

Defined Diarrhea and Dysentery. Stage of HIV/AIDS – WHO criteria.

Blood specimen (baseline and every six months) for the measurement of CD4+. A sample of 300 women was randomly selected for the measurement of viral load.

Cause of death was approximated by using verbal-autopsy techniques by conducting standardized interviews with relatives, reviewing medical records, or both.

Cause of death was ascertained in a blinded fashion.

ATTRITION BIAS: Low

The authors do not state the number of people that were lost to follow-up.

All analyses were conducted according to the intention to treat.

STUDY FINDINGS

Outcomes	Placebo n = 267	Multivitamins n = 271	Multivitamins & vitamin A n = 268	Vitamin A n = 272
	No. of events	No. of events	RR (95%CI)	No. of events
Progression to stage 4 or death from AIDS-related causes	83	67	0.71 (0.51-0.98)	79
Death from AIDS-related causes	66	52	0.73 (0.51-1.04)	65
Progression to stage 4	31	18	0.50 (0.28-0.90)	23
Progression to ≥stage 3	166	163	0.72 (0.58-0.90)	165
≥2-stage increase	145	131	0.66 (0.52-0.84)	134

	Placebo n = 267	Multivitamins n = 271	Multivitamins & vitamin A n = 268	Vitamin A n = 272
Outcomes	Mean value	Mean difference (95%CI)	Mean difference (95%CI)	Mean difference (95%CI)
CD4+ cell count	449± 255	48 (10 to 85)	41 (4 to 77)	-15 (-45 to 14)
Viral load	4.67±0.86	-0.18 (-0.32 to -0.03)	-0.07 (-0.21 to 0.09)	-0.03 (-0.17 to 0.11)

COMMENTS

Multivitamins delayed the onset of disease progression. Adding vitamin A to the multivitamin supplement reduced the benefit of the latter regimen.

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